



**AMCP**

Optimizing medicine.  
Improving lives.

# Legislative Days 2025

Washington, D.C.

**Monday, May 12 – Wednesday, May 14**



# AMCP

Optimizing medicine.  
Improving lives.

## First Timers' Session

Adam Colborn, AMCP

9:00am-9:30am

# What to expect

- Today:
  - Training on priority legislation, using your AdvocacyDay app, and how to conduct a Hill meeting.
  - Receive leave-behind folders for tomorrow.
  - Awards reception and dinner, presenting Sen. Capito and Shaheen with awards. Attire is business.
- Tomorrow:
  - Hill meetings all day. Attire is business.
  - Most meetings will not have an AMCP staff member.
  - Luggage storage, rest area, and lunch at Top of the Hill hospitality suite. Transportation from hotel via limo bus, departing every 30 minutes from 8am – 12pm.

# Common terms

- **Ask** – the request you are making of your Members of Congress (i.e., “please co-sponsor the MVP Act”).
- **Leave-behind** – informational material you give to the staffer during the meeting; the staffer keeps this material.
- **Sponsor** – the Member of Congress who introduced a bill, also referred to as “leading” the bill.
- **Co-sponsor** – A Member of Congress who has committed to supporting the bill; co-sponsorship is the gold standard of support.
  - A Member who co-sponsored at the time of introduction is called an “original” co-sponsor.

# Common terms

- **Fly-in** – This type of event, where advocates convene in DC for many Hill meetings on the same day. Most groups have their own name for it, but Hill staffers may ask if you’re part of a “fly-in.”
- **Mark-up** – A committee process where a bill is considered and amended. Considered a step towards passage. More common in the House than the Senate. Staffers may ask if a bill has been “marked up.”
- **Score** – The estimated cumulative cost of the bill over 10 years, as determined by the Congressional Budget Office (CBO). Staffers (particularly Republican offices) may ask if a bill has been “scored.”

# What if I can't advocate for one of the bills?

Sometimes, an AMCP advocate may have employer restrictions or other reasons that they cannot advocate for a certain bill. This is not uncommon and is easily managed.

- Let AMCP staff know.
- If you have other advocates in your team, turn the conversation over to another team member if possible.
- If you are solo, take the issue brief out of your leave-behind and skip that portion of the conversation.
- Remember that you are here in your **individual and personal** capacity, **not** as a representative of your employer.

# Congressional office hierarchies

- In descending order of authority
  - Member of Congress
  - Chief of Staff
  - Legislative Director
  - Legislative Assistant/Policy Aide
  - Legislative Correspondent
  - Staff Assistant
  - Intern
- Other titles you may see:
  - Fellow
  - Scheduler
  - Communications Director

# Getting around the Hill

- Longworth and Rayburn office numbers are 4 digits long, the first digit indicates building and the second indicates floor.
  - 1 means Longworth, 2 means Rayburn.
  - Examples: “1345 Longworth” means Longworth building, 3rd floor, office 45. “2210 Rayburn” means Rayburn building, 2nd floor, office 10.
  - We will always put the building name with the office number. You can ignore the first digit in Longworth and Rayburn addresses.
- Cannon uses 3-digit office numbers and does not have a building identifier.
  - Example: “422 Cannon” means Cannon building, 4th floor, office 22.



# Getting around the Hill

- Easiest method is to walk outside between buildings. This is necessary for going between the House and Senate.
- The Capitol Subway System, connecting Senate and House offices to the Capitol Building, is not accessible by the public. It is for staff only.
- There are hallways on the lowest levels of both the Senate and House office complexes that connect to the other buildings in that complex but do not connect to the other complex.
  - Unless there is an urgent need such as back-to-back meetings, we recommend against using these tunnels. They are difficult to navigate without familiarity.



# Questions and discussion



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# Advocacy in a Divided Time

David Lusk, Key Advocacy

**9:30am-10:30am**



# Effective Advocacy in



# Challenging Times

Legislative Days 2025 – May 13, 2025

# When was the first Capitol Hill fly-in?



March 22, 1922 - Lawrence Sperry

Aviation pioneer who invented:

- Autopilot
- Artificial horizon
- Capitol Hill fly-ins!!!

## Are fly-ins effective?

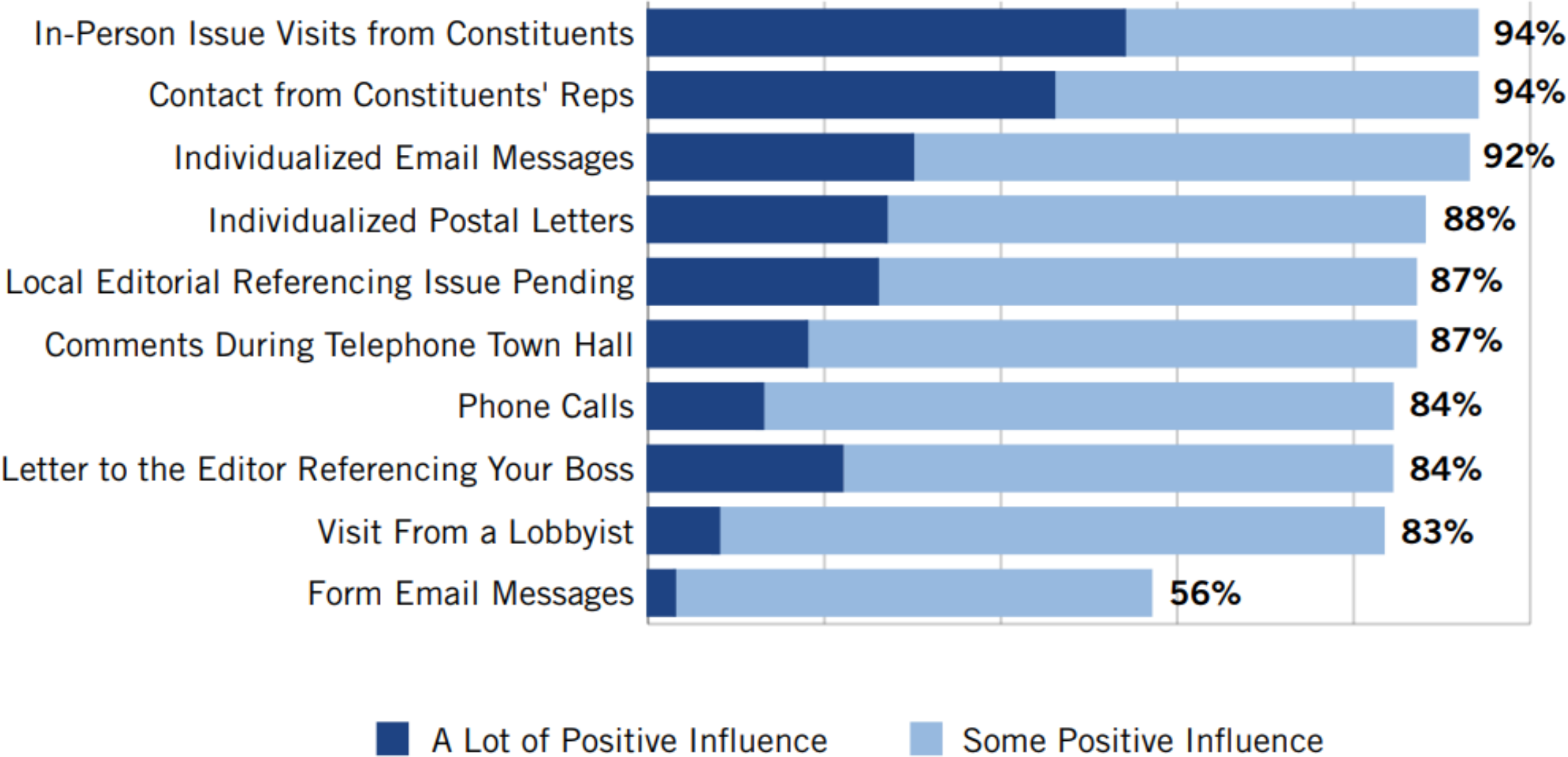
National Journal's Advocacy Fly-In Deck



Fly-ins have ~~increased exponentially in the~~ **last decade**, and members of Congress consistently **say they prefer to hear from fly-in visitors**, who often have firsthand knowledge of the impact of government policies.



# Congress Values Constituent Viewpoints



# Effective Advocacy in Challenging Times

Ever feel frustrated or disappointed  
with results of advocacy efforts?



**Capitulation**  
**Day...**

# Capitulation Day...

In other words, the president has caved. He may have been swayed by market wobbles but it seems more plausible that dire warnings from retailers about empty shelves – backed up by data showing shipments into US ports collapsing – may have strengthened the hands of trade moderates in the administration.

Trump might claim China tariff victory - but this is Capitulation Day

Heather Stewart

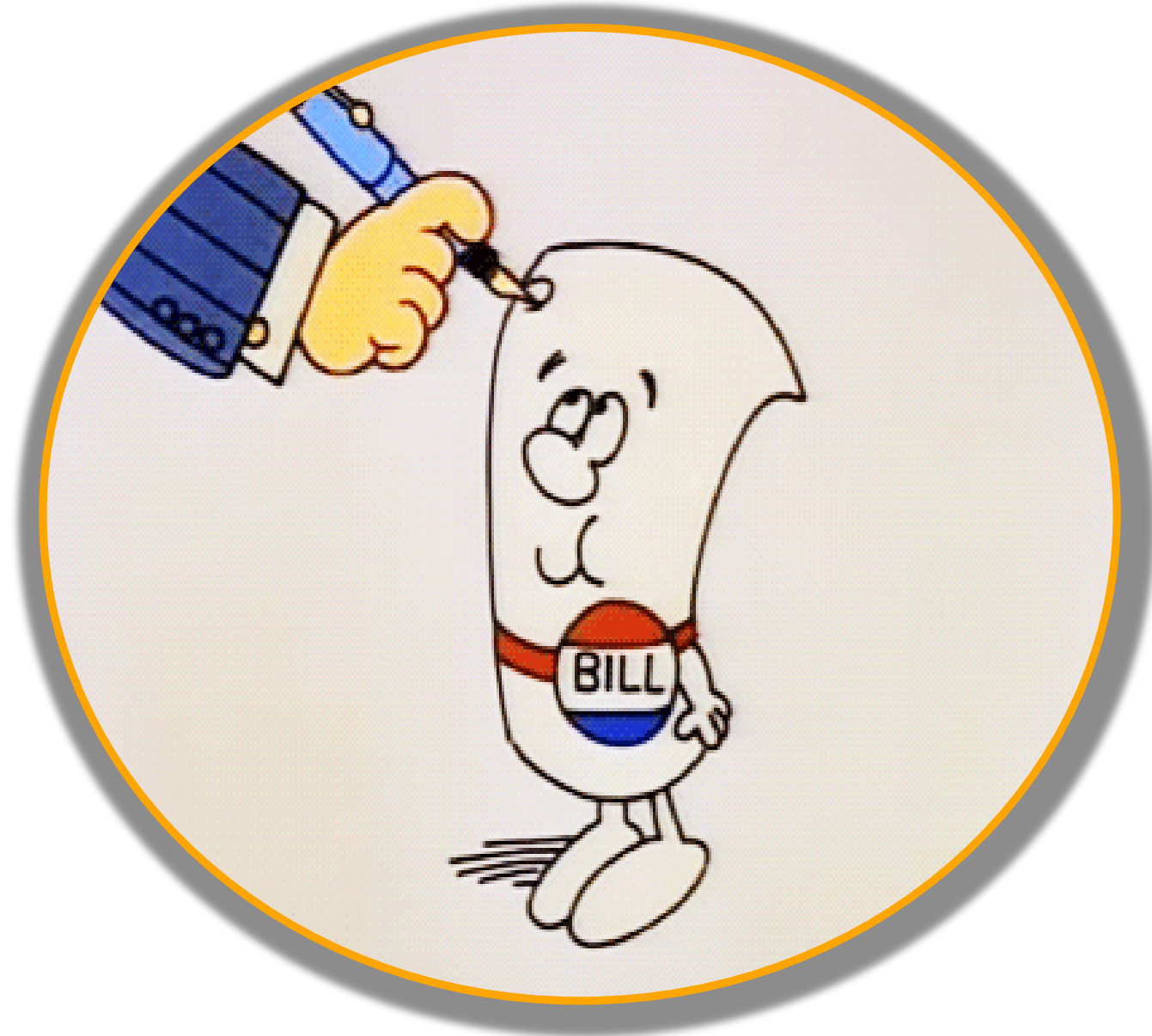
Economics editor

The president's retreat suggests he might negotiate elsewhere, but leaves corrosive uncertainty in its wake

- [China and US agree 90-day pause to trade war](#)
- [Business live - latest updates](#)



# Average Enactment Interval



# A Competitive Legislative Landscape

More Organizations & More Advocates  
Conducting Congressional Fly-Ins



150



200



700



1,300



150



250 (Mar), 400 (Nov)



700 (May), 150 (Nov)



7 Organizations

# A Competitive Legislative Landscape

Increased Emphasis on Relationship-Based Advocacy Year-Round





# A Competitive Legislative Landscape

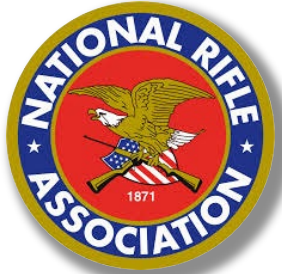
## Manage Your Expectations

**opengov** FOUNDATION **From Voicemails to Votes**

- Nearly impossible to change a lawmaker's mind overnight.
- Policy change can require “continuing the conversation” over time, not just a one-time activism spike.
- Maybe they won't switch from no to yes but you can convince them to not say anything.

# A Competitive Legislative Landscape

Who Are DC's Most (Repeatedly) Admired *Advocacy* Organizations?



**Why?**

What is the *Overarching Goal* of Advocacy?



Building relationships with government offices





## Build Rapport & Relationships

- Naturally organic for some
  - Individual interpersonal skills
  - Lawmakers supportive of our industry
  - In/out-of-favor party or politicians
- More conversational interactions
- Substantial dividends over long term

# Build Rapport & Relationships

## **Strong Correlation:**

Effort Invested

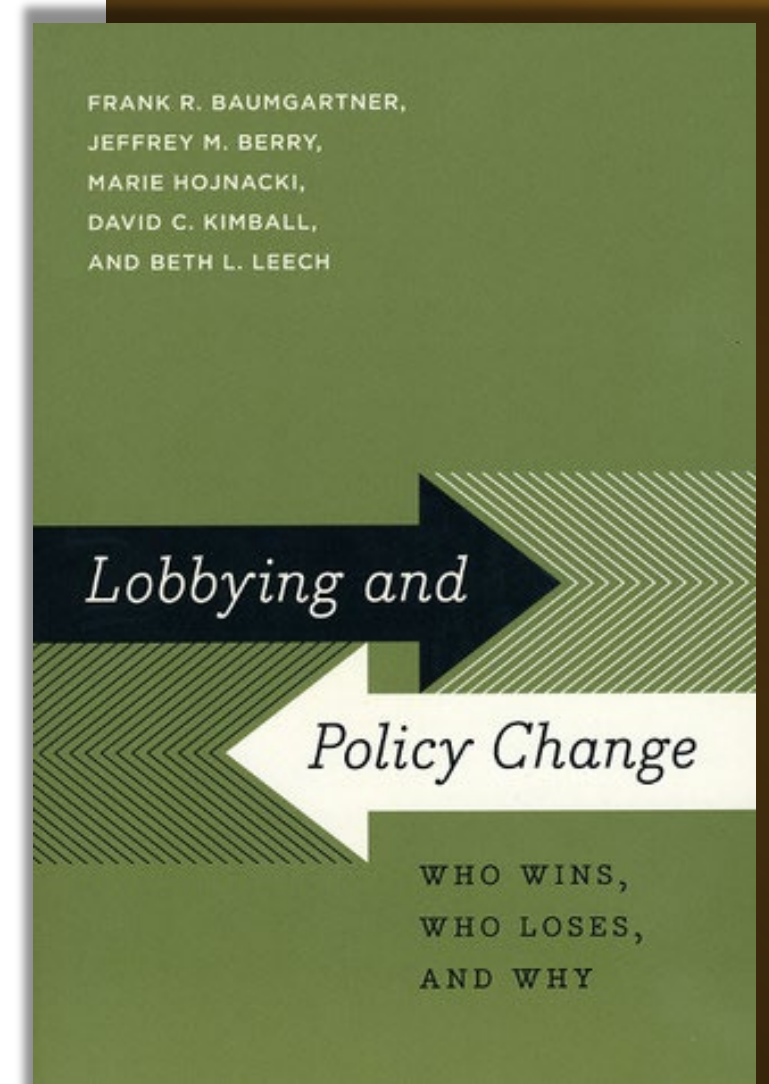
Positive Policy Outcomes

Are your advocacy efforts tailored toward building *relationships* with legislative offices or only making asks?

# Effective Advocacy: More Than Form Emails

## *Lobbying and Policy Change: Who Wins, Who Loses and Why*

- Those with large budgets or PAC dollars won only *half* the time.
- Better predictor of success?
- Those who built relationships!



A close-up photograph of a person's hand holding a small green seedling with soil. The hand is positioned on the right side of the frame, with fingers gently cradling the base of the plant. The seedling has several vibrant green leaves and a thin stem. The background is a soft, out-of-focus landscape with a warm, golden light, suggesting a sunrise or sunset. A large, semi-transparent white circle is overlaid on the left side of the image, containing text.

## Relationships Don't Materialize Overnight


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The best time to plant a tree  
was 20 years ago.

The second best time is now.

- Chinese Proverb

# Build Rapport & Relationships

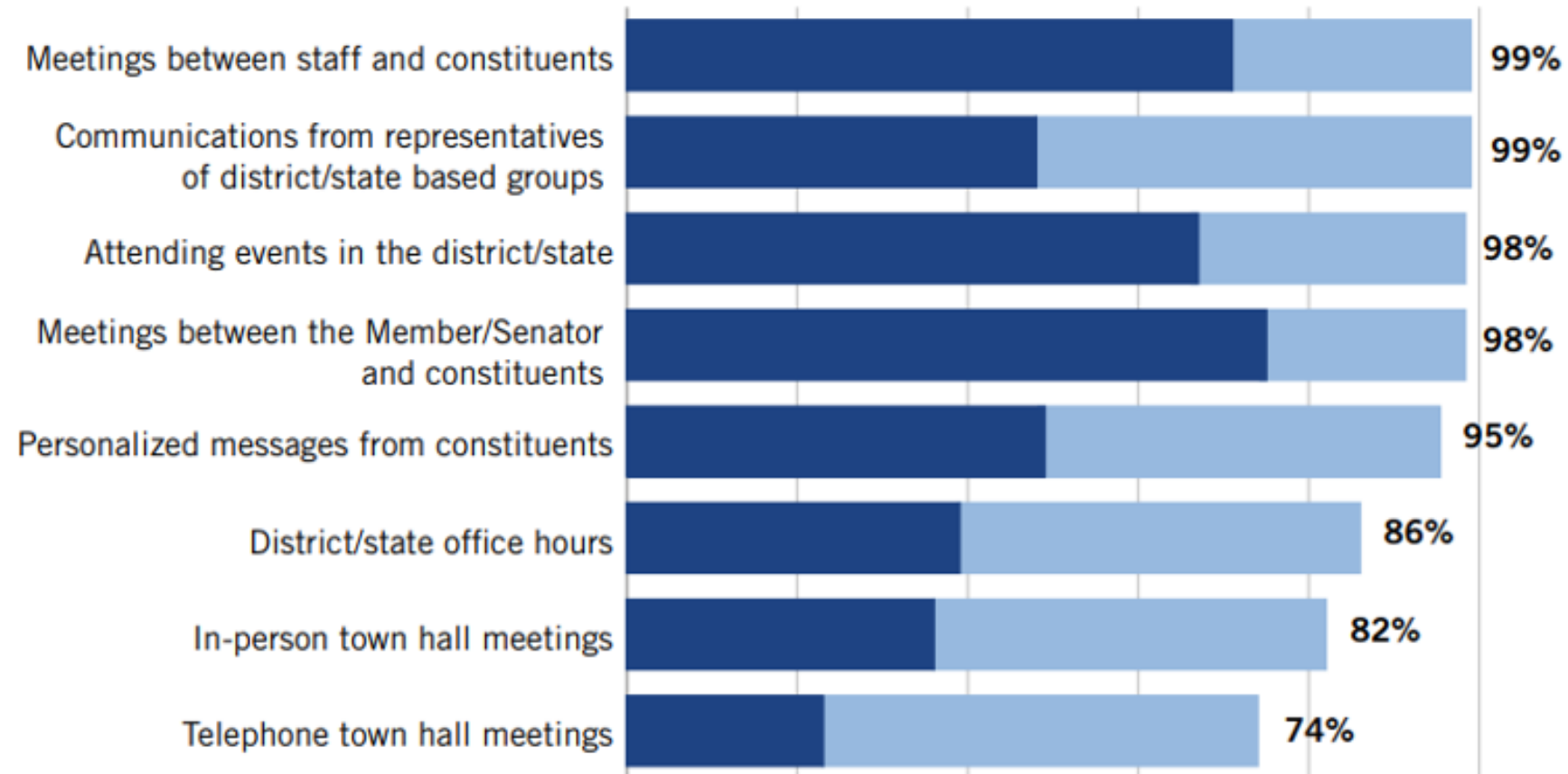
- Thank them publicly for a recent vote, decision or comment you support.
- Engage & show appreciation when possible via social media.
- Seek to become a valuable point of contact in the legislative district.
- Building relationships  giving when possible.
- How can your interactions provide value?
- How can you build rapport “across the aisle”?



# Build Rapport & Relationships Via Diversified Engagement

Very Important      Somewhat Important

**In your opinion, how important is each for understanding constituents' views & opinions?**

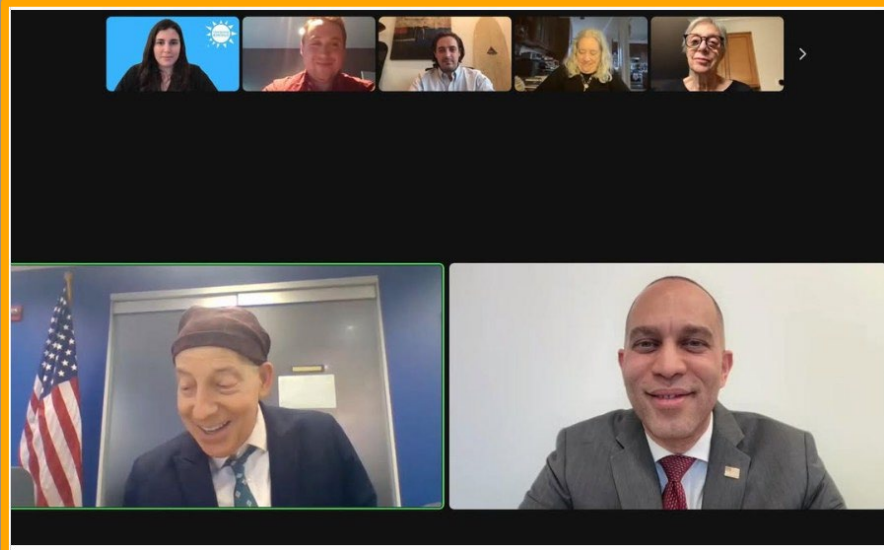


# Value of Diverse Engagement

In what ways have you engaged congressional offices?



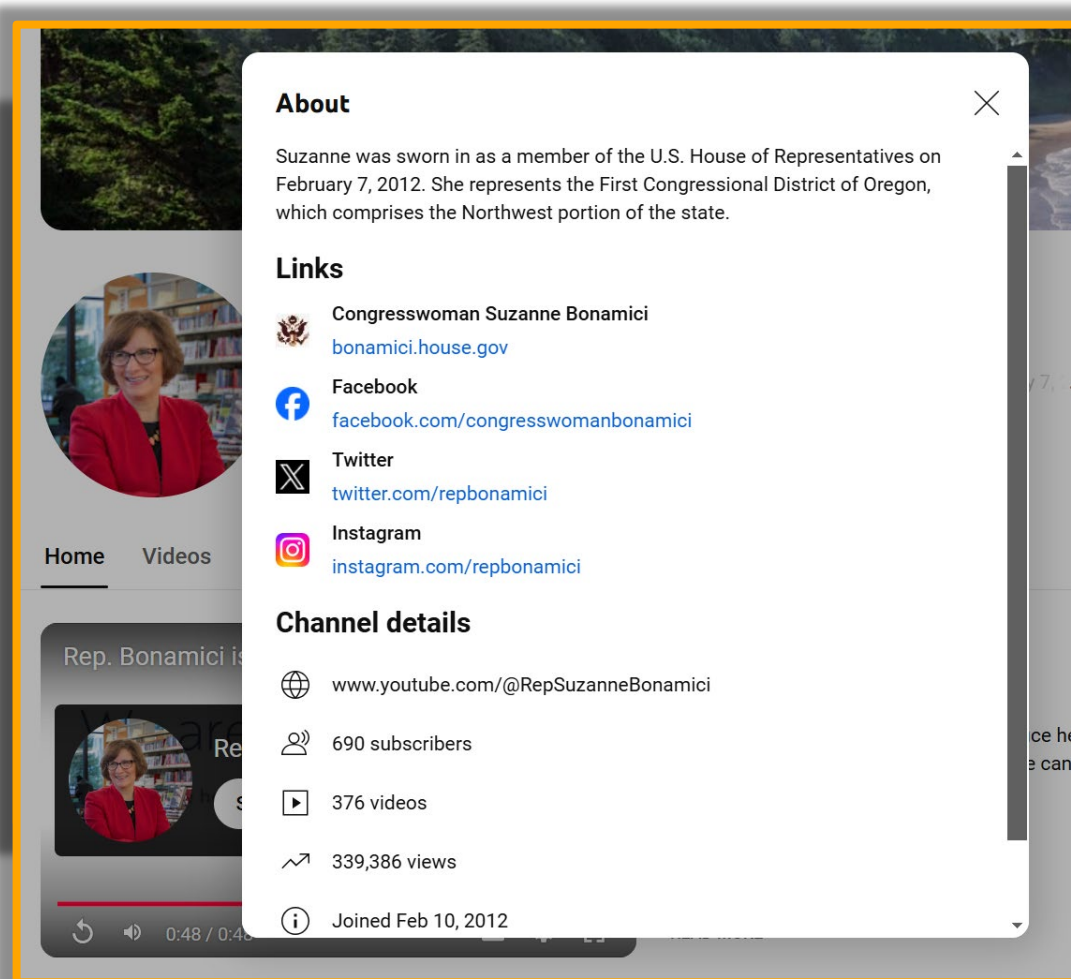
Do you leverage tactics that play to your individual strengths?



# Value of Diverse Engagement

## Follow Their Social Media Accounts & Comment / Post

- Offers other means for engaging MoCs
- Suggests their most pressing concerns
- Makes you stand out as an “early adopter”

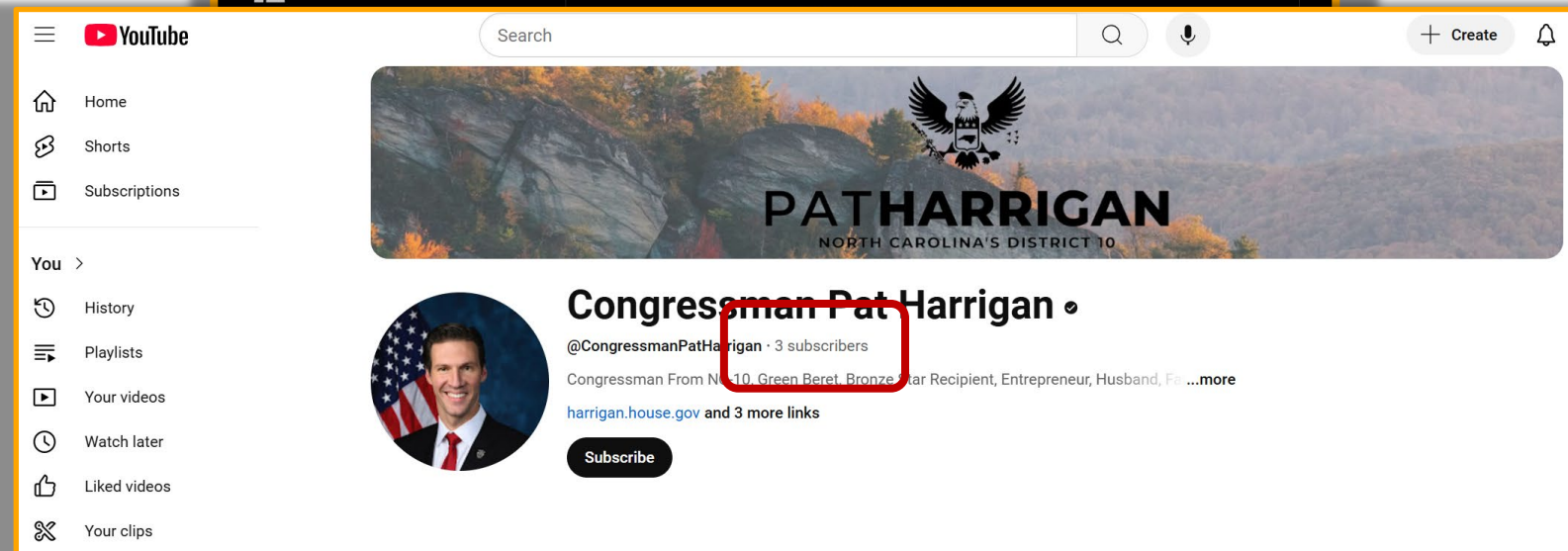




# Value of Diverse Engagement

## Follow Their Social Media

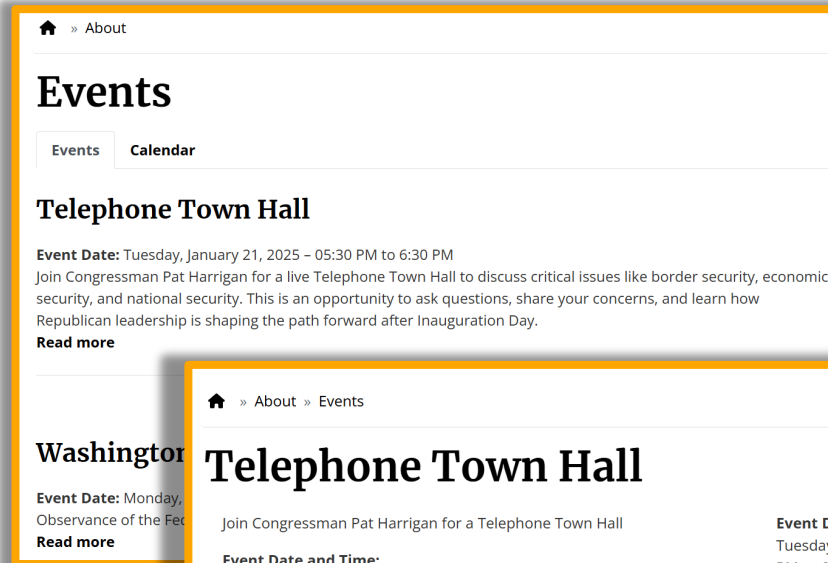
- Offers other means for engaging MoCs
- Suggests their most pressing concerns
- Makes you stand out as an “early adopter”



# Value of Diverse Engagement

## Attend Upcoming Events / Appearances & Speak Up

- Exhibits engagement, polite persistence & interest in their work
- Connects a face to a name
- Effective relationship building tactic



Home » About

### Events

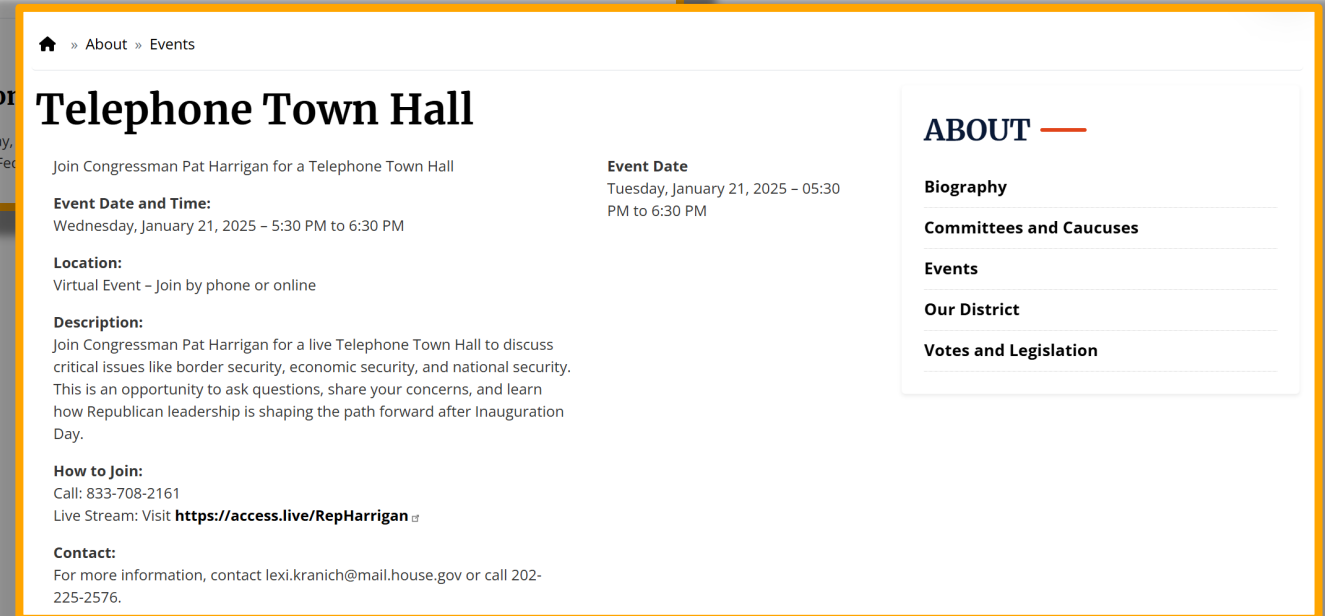
Events Calendar

#### Telephone Town Hall

**Event Date:** Tuesday, January 21, 2025 – 05:30 PM to 6:30 PM  
Join Congressman Pat Harrigan for a live Telephone Town Hall to discuss critical issues like border security, economic security, and national security. This is an opportunity to ask questions, share your concerns, and learn how Republican leadership is shaping the path forward after Inauguration Day.  
[Read more](#)

Washington

**Event Date:** Monday, Observance of the Fed  
[Read more](#)



Home » About » Events

## Telephone Town Hall

Join Congressman Pat Harrigan for a Telephone Town Hall

**Event Date**  
Tuesday, January 21, 2025 – 05:30 PM to 6:30 PM

**Event Date and Time:**  
Wednesday, January 21, 2025 – 5:30 PM to 6:30 PM

**Location:**  
Virtual Event – Join by phone or online

**Description:**  
Join Congressman Pat Harrigan for a live Telephone Town Hall to discuss critical issues like border security, economic security, and national security. This is an opportunity to ask questions, share your concerns, and learn how Republican leadership is shaping the path forward after Inauguration Day.

**How to Join:**  
Call: 833-708-2161  
Live Stream: Visit <https://access.live/RepHarrigan>

**Contact:**  
For more information, contact [lexi.kranich@mail.house.gov](mailto:lexi.kranich@mail.house.gov) or call 202-225-2576.

### ABOUT

- Biography
- Committees and Caucuses
- Events
- Our District
- Votes and Legislation

# Value of Diverse Engagement

Attend Upcoming

- Exhibits engagement, polite persistence & interest in their work
- Connects a face to a name
- Effective relationship building tactic
- (but learn how to take better selfies!!)



# Value of Diverse Engagement

## Attend District “Office Hours” & Open Houses

- Provides a more casual, social environment to interact
- Presents opportunities to engage with staff
- Affords open discussion, asking questions, or information sharing / updates

[Home](#) » [About](#) » [Events](#)

## Hickory District Office Open House

District Office Open House

**Event Date and Time:**  
Friday, February 21, 2025 - 1:00 PM to 3:00 PM

**Location:**  
Congressman Harrigan's Hickory District Office  
800 17th Street NW  
Hickory, North Carolina 28601

**Description:**  
You're invited to an Open House at Congressman Pat Harrigan's Hickory District Office! Stop by to meet the Congressman and his team, discuss your concerns, and learn about the services available to constituents.

**Contact:**  
For more information, call 202-225-2576.

**Event Date**  
Friday, February 21, 2025 - 01:00 PM to 2:30 PM

**Address**  
800 17th Street NW  
Hickory , North Carolina 28601  
United States

**Get directions** [↗](#)

# Value of Diverse Engagement

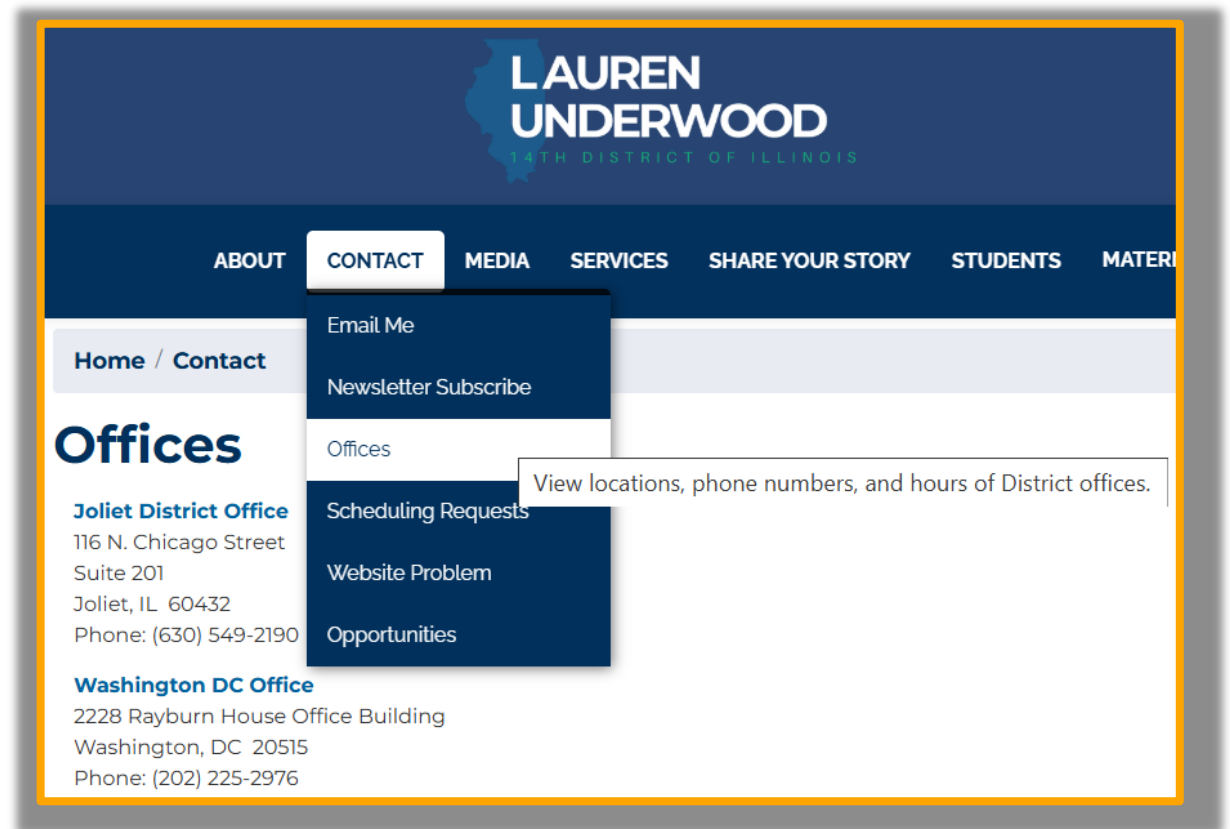
## Attend District “Office Hours” & Open Houses

- Freshmen lawmakers often open to “meet & greet” engagements
- Look for & emphasize any commonalities in your background that align with your MoC
- If needed: Identify any connections to your MoC within your personal network who might conduct an introduction

# Value of Diverse Engagement

## Request an In-District Meeting or Appearance

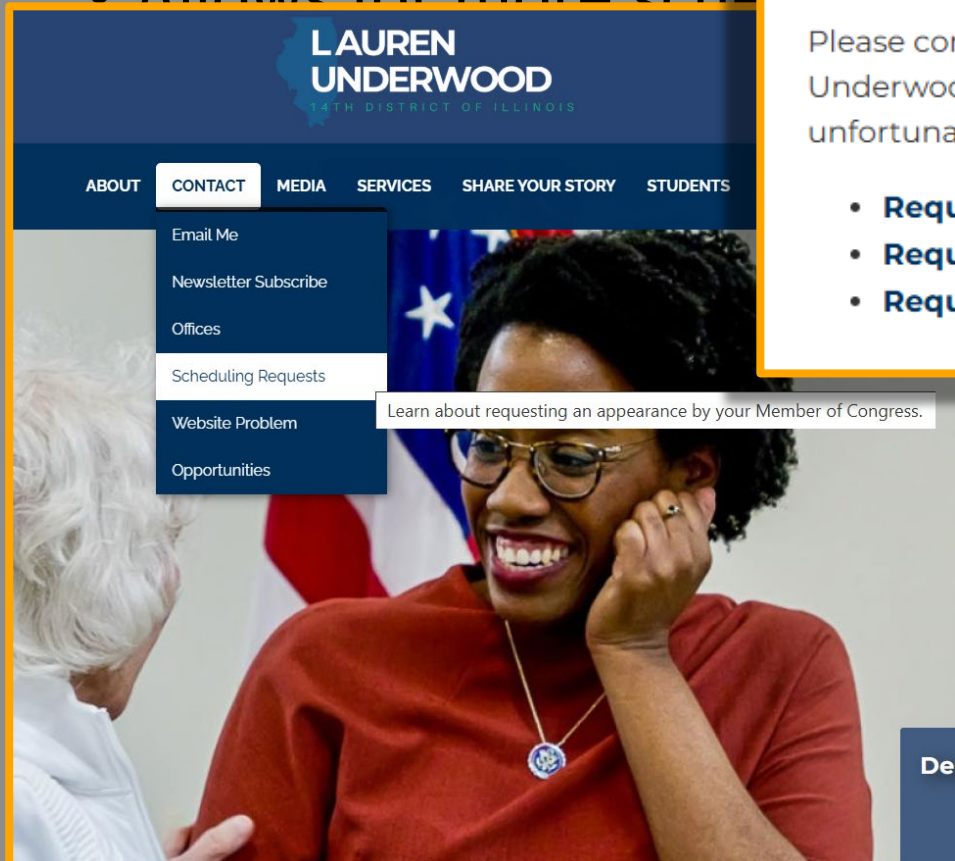
- Allows for more schedule flexibility
- Offers “home field” advantage
- Enables you to “showcase” your workplace or other items of interest



# Value of Diverse Engagement

## Request a

- Allows for more sche



[Home](#) / [Contact](#)

## Scheduling Requests

Please complete one of the following forms to submit a scheduling request for Representative Underwood's time. We kindly request at minimum two week's notice for all requests and are unfortunately unable to guarantee availability. Thank you for your understanding.

- [Request a Meeting with Congresswoman Underwood](#)
- [Request Congresswoman Underwood Participate in Your Event or Speaking Engagement](#)
- [Request Congresswoman Underwood Visit Your Business or Other Location](#)

Why?



# Three Types of Lawmakers

- **Champion**
- **Uncommitted**
- **Challenging**



# Three Types of Lawmakers

- Desired outcomes
- Framing your ask
- Framing your story
- How many stories you need
- Understand key traits for insights into finding common bonds



*“If you talk to a man in a language he understands, that goes to his head. If you talk to him in his language, that goes to his heart.”*

- Nelson Mandela



# Stress Stories Over Statistics

**RollingStone**

*“...nothing is more powerful than the stories of the people affected.*

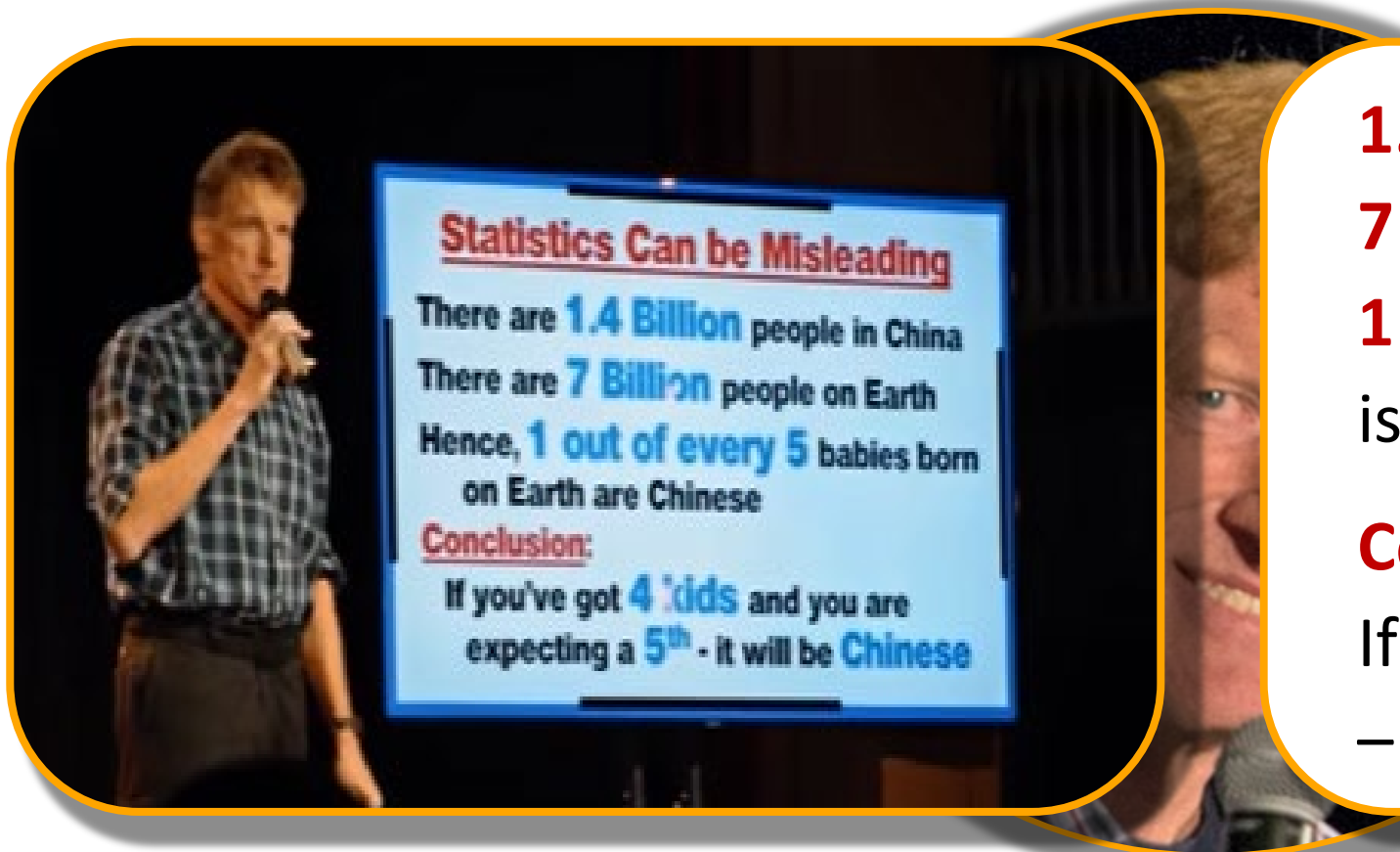
*You can roll out statistics and timetables, but the consequences – the emotional connection to the rest of the public – is really what weighed in.”*



**-- Speaker Emeritus Nancy Pelosi**

# Stress Stories Over Statistics

## Statistics Can Be Misleading



**1.4 billion** people in China  
**7 billion** people on Earth  
**1 of every 5** babies born on Earth  
is Chinese

**Conclusion:**  
If you have **4 kids** & expect a **5<sup>th</sup>**  
– it will be **Chinese**

Engineer Turned Comedian

Don McMillan

# HOW STORYTELLING AFFECTS THE BRAIN



## NEURAL COUPLING

A story synchronizes the listener's brain with the teller's brain.

## MIRRORING

Mirror neurons enable listeners to mirror experience

## CORTICAL ACTIVITY

Two areas of the brain are activated when processing facts. Stories activate many additional areas such as the motor

## DOPAMINE

The brain releases dopamine in response to an emotionally-charged event, resolution of conflict, or

The One Secret?

Finding a Common Bond



..——..

WHEN YOU  
TALK, YOU ARE  
ONLY REPEATING  
WHAT YOU  
ALREADY KNOW.  
BUT IF YOU  
LISTEN, YOU  
MAY LEARN  
SOMETHING NEW.  
- DALAI LAMA



# Making Mid-Meeting Modifications

Case Study:  
SHRM Advocacy Team





# Inside The Numbers

## 119<sup>th</sup> Congress – Unified GOP Control (in theory)



**53**

**47** (45D + 2I)

The Senate

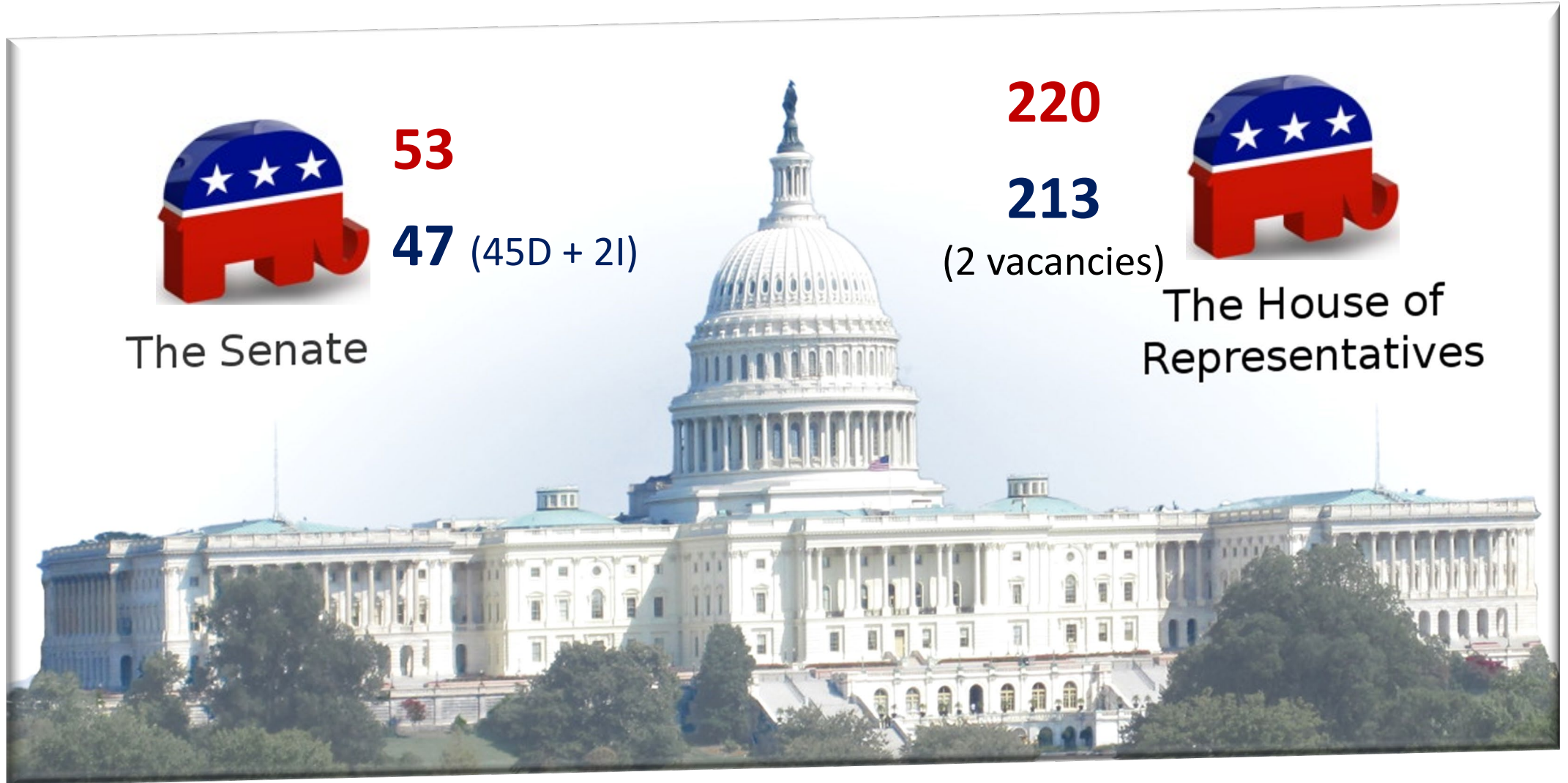
**220**

**213**

(2 vacancies)



The House of  
Representatives



# Inside The Numbers

## Change Elections

- 2024 was 6<sup>th</sup> consecutive, 9<sup>th</sup> of last 10
- Narrow House & Senate majorities the norm
- Freshmen & second termers can wield outsized influence
- Trend of recurring change elections should continue
- Slim or threatened majorities can prove advantageous

POLITICS

## House Republicans settle fight over remote votes for new parents after Johnson-Luna standoff

### Luna wins battle with GOP leadership over proxy vote bill

House Republican leadership sought to block Florida Rep. Anna Paulina Luna's discharge petition, paving the way for new moms and dads in the chamber to vote by proxy for up to 12 weeks.

A discharge petition — an uncommon method for forcing legislation to the House floor that bypasses leadership — filed by Luna, officially garnered 218 signatures from fellow House members, her office announced last month, reaching the threshold needed to send the measure to the floor without the speaker.

Luna prevailed in blocking leadership's rule change, 222 to 206.

## Rep. Anna Paulina Luna leaves House Freedom Caucus over proxy voting for new parents



**Sudiksha Kochi**  
USA TODAY

March 31, 2025 | Updated April 3, 2025, 9:53 a.m. ET

## Freedom Caucus loses another member to internal divisions

## Kevin McCarthy ousted as House Speaker in historic vote

## Mike Johnson Elected House Speaker After Republican Holdouts Change Their Votes in the First Round

**Alexandria Ocasio-Cortez Defeats Joseph Crowley in Major Democratic House Upset**

**29-year-old Alexandria Ocasio-Cortez makes history as the youngest woman ever elected to Congress**

**The New York Times**



Alexandria Ocasio-Cortez won the Democratic primary in New York's 14th Congressional District.

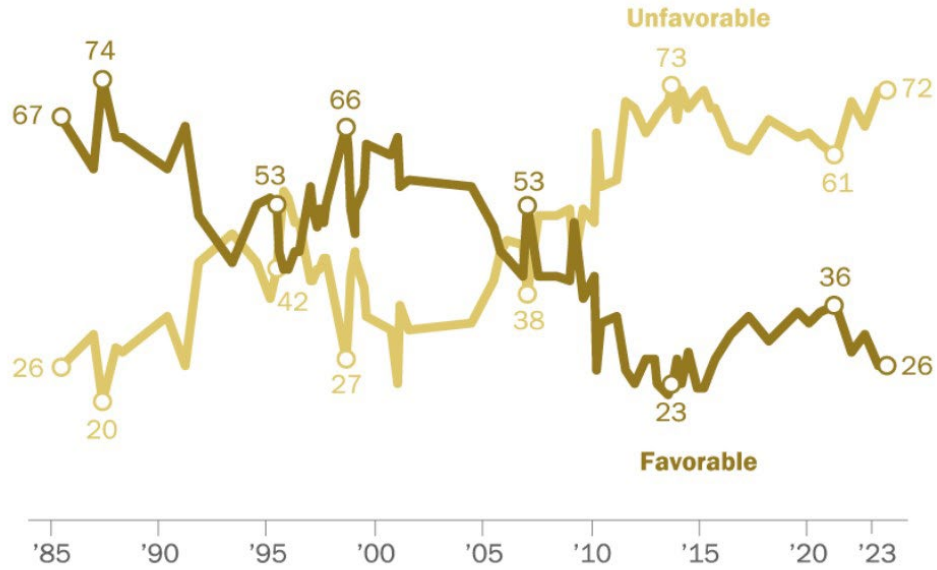
**'The Squad' Rankles, but Pelosi and Ocasio-Cortez Make Peace for Now**

**AOC and her fellow 'Squad' members all win re-election to Congress**

The Bronx native spoke about her campaign's mission a day after winning the Democratic primary with her defeat of Representative Joseph Crowley. *New York Times* by Jonathan Martin

## Most Americans continue to have a negative view of Congress

% who say they have a(n) \_\_\_\_ opinion of Congress



Note: No answer responses not shown.

Source: Survey of U.S. adults conducted July 10-16, 2023.

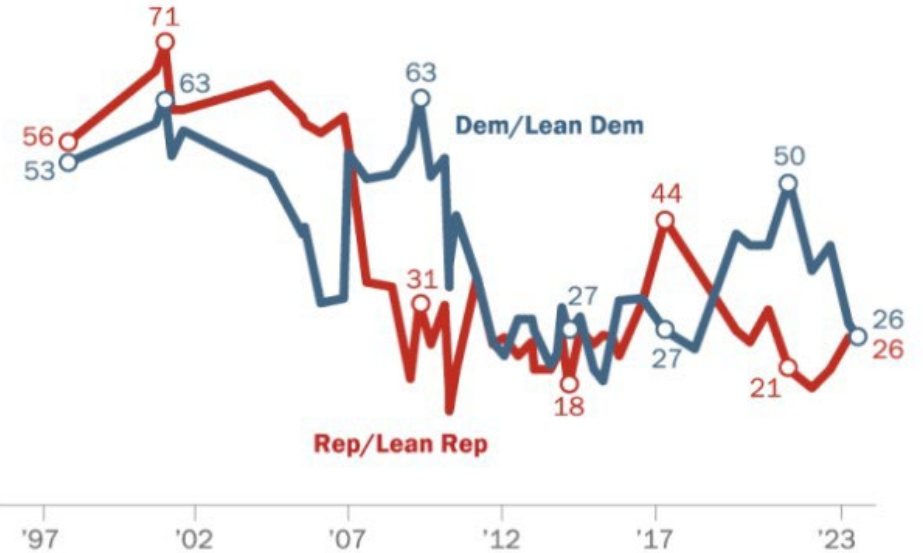
Trend sources: Pew Research Center's American Trends Panel (2019-2023), Pew Research Center phone surveys (2018 and earlier).

"Americans' Dismal Views of the Nation's Politics"

PEW RESEARCH CENTER

## About a quarter of both Democrats and Republicans have a favorable view of Congress

% who say they have a *favorable* opinion of Congress



Source: Survey of U.S. adults conducted July 10-16, 2023.

Trend sources: Pew Research Center's American Trends Panel (2019-2023), Pew Research Center phone surveys (2018 and earlier).

"Americans' Dismal Views of the Nation's Politics"

PEW RESEARCH CENTER

## 2025 Honesty and Ethics of Professions Ratings

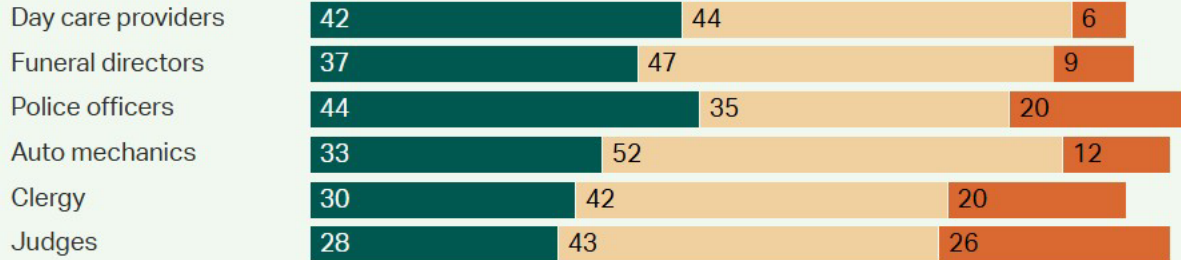
Please tell me how you would rate the honesty and ethical standards of people in these different fields -- very high, high, average, low or very low?

■ % High/Very high ■ % Average ■ % Low/Very low

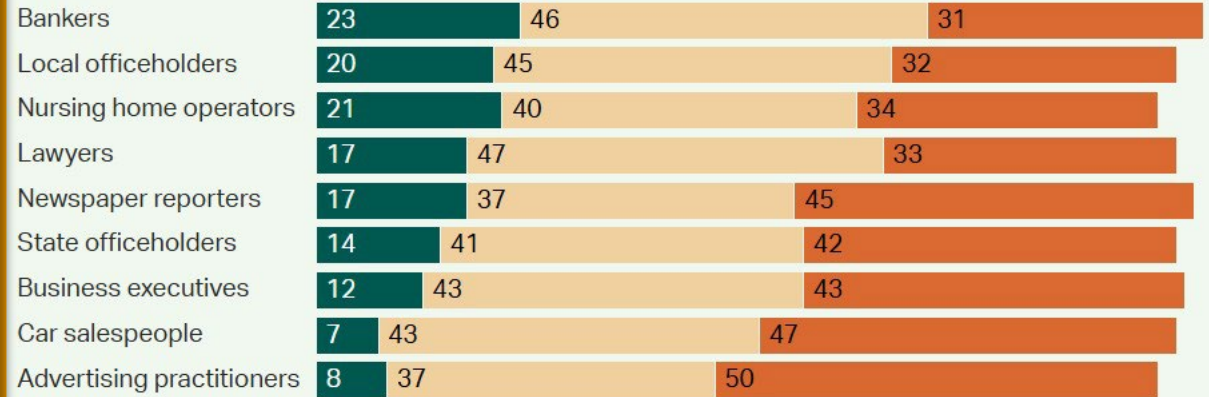
### Majority positive



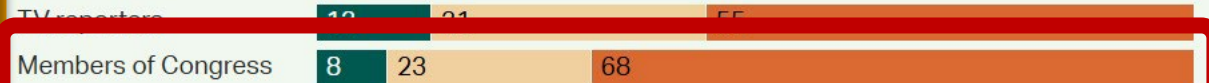
### Net positive



### Net negative



### Majority negative



CONGRESS

## Shutdown ends after Trump signs budget

Senate Democrats

Seventy-  
package,

“What makes Democrats proudest of this bill is that after a decade of cuts to programs that help the middle class, we have a dramatic reversal,” added Schumer. “Funding for education, infrastructure, fighting drug abuse, and medical research will all, for the first time in years, get very significant increases, and we have placed Washington on a path to deliver more help to the middle class in the future.”

ority Leader  
Senate Majority



“This is a great victory for our men and women in uniform. Republicans and Democrats joined together to finally give our troops the resources and our generals the certainty to plan for the future,” said Speaker Paul Ryan. | Jacquelyn Martin/AP Photo

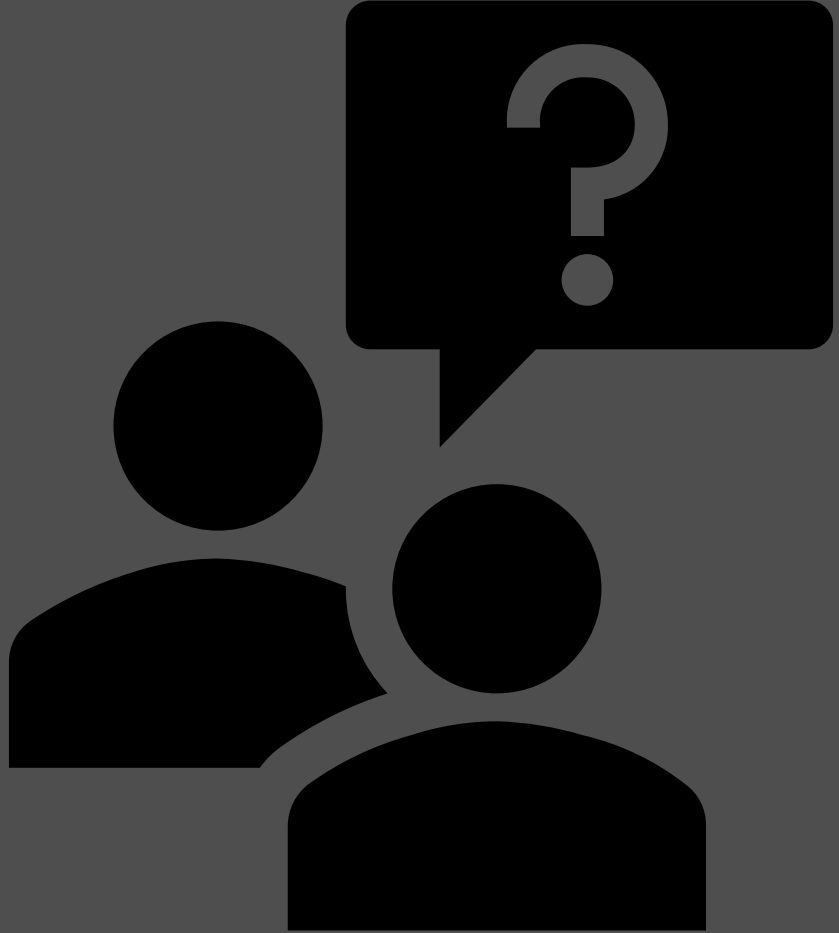
## **\$122 Million Funding Increase**

**2014**

Legislation is passed and signed which provided an additional \$122 million in the FY14 budget for Alzheimer's research, education, outreach and caregiver support. This included \$100 million for research, \$20 million more than was in the president's FY14 budget request.

- Piggybacked omnibus appropriations bills
- Record \$100 million increase for NIH research
- 2013 Advocacy Forum attended by 800 advocates, from all 50 states
- 2,600 meetings in DC & in-district by Alzheimer's Association Ambassadors, advocates & staff





“I calculated once how many times I fell during my skating career – 41,600 times. But here’s the funny thing: I got up 41,600 times.

That’s the muscle you have to build in your psyche – the one that reminds you to just get up.”

Scott Hamilton

Retired Figure Skater & Olympic Gold Medalist





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Improving lives.

# **Key Federal Court Cases and Their Impact on Healthcare – Where Advocacy Fits In**

**Haider Andazola, J.D. Counsel - Manatt, Phelps & Phillips**

**11:00am-12:00pm**

# Learning Objectives



Review the structure of the judiciary and the administrative law principles that apply to healthcare law.



Discuss recent seminal cases that affect healthcare law and key ongoing litigation with significant implications for healthcare.



Identify opportunities to influence litigation and/or shape the outcome of litigation.

# Continuing Pharmacy Education Credit



The Academy of Managed Care Pharmacy (AMCP) is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. This activity is accredited to provide 1.0 contact hours of continuing pharmacy education (CPE) credit.

Instructions to claim credit will be emailed

- ✓ Obtain the access code at the end of the presentation
  - ✓ Login to [amcplearn.org](https://amcplearn.org)
  - ✓ Submit by May 23, 2025

# Financial Relationship Disclosures

Role	Reported Relevant Financial Relationships
<b>Haider Andazola</b> <i>Faculty</i>	Disclosed no relevant financial relationships.
<b>Drake Reiter</b> <i>Peer Reviewer</i>	Disclosed no relevant financial relationships.
<b>Kristine Paschalis</b> <i>Staff Planner</i>	Disclosed no relevant financial relationships.
<b>Tyler Thorne</b> <i>Staff Reviewer</i>	Disclosed no relevant financial relationships.

- If applicable, relevant financial relationships have been mitigated and documented.
- Content has undergone a peer review to ensure content validity.

# AMCP Antitrust Guidelines

- AMCP's policy is to comply fully and strictly with all federal and state antitrust laws
- This session will be monitored for any antitrust violations and will be stopped by the session monitor if any such violation occurs
- Please refer to the final program or [www.amcp.org/antitrust](http://www.amcp.org/antitrust) for more information

# Introduction to the Federal Judiciary and Administrative Law



## Polling Question1

### 1. Which of the following best delineates the roles of federal District Courts, Circuit Courts, and the Supreme Court?

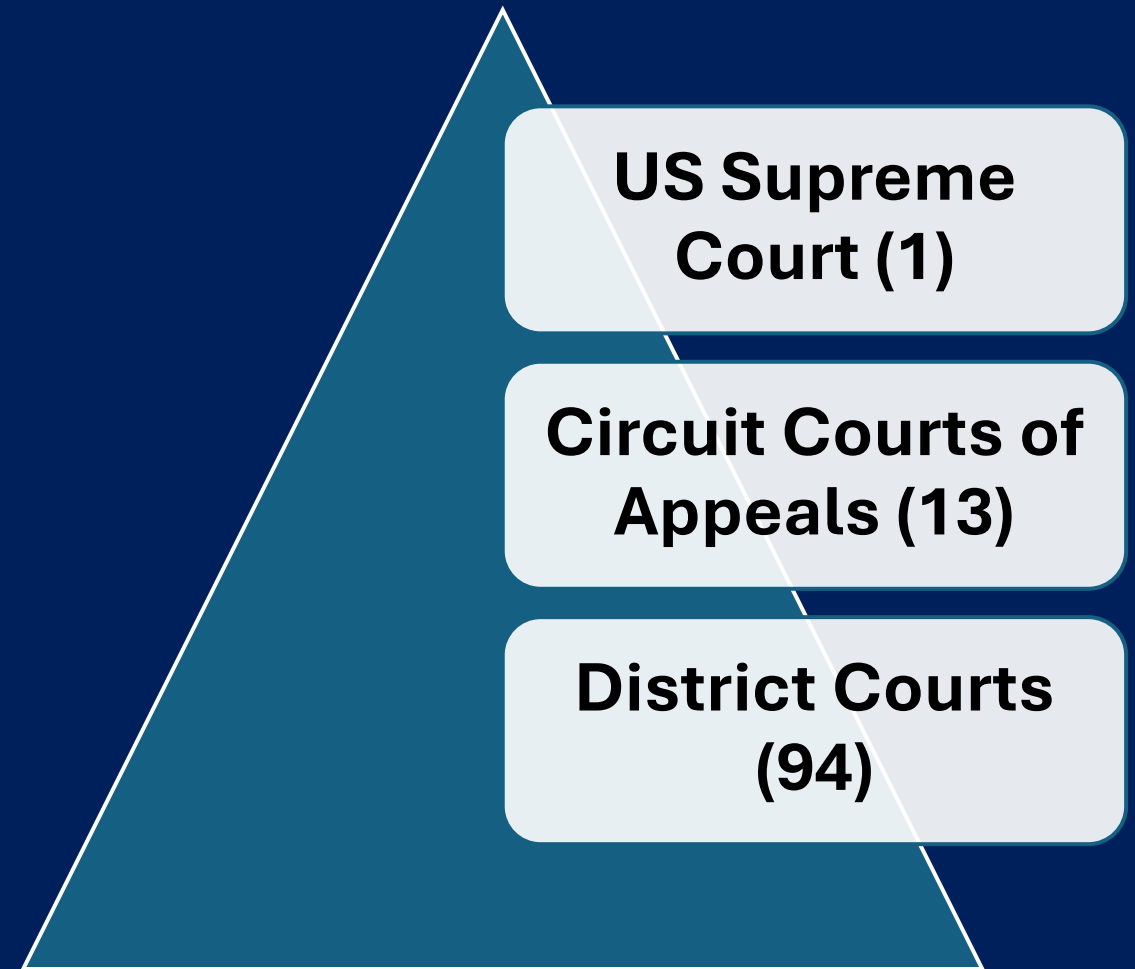
- a) District Courts handle trials and legal disputes, Circuit Courts review appeals and may modify decisions, and the Supreme Court resolves select cases as the final authority.
- b) Circuit Courts initiate trials, District Courts handle appeals, and the Supreme Court reviews all lower court decisions.
- c) The Supreme Court conducts jury trials, Circuit Courts review constitutional issues, and District Courts focus solely on administrative cases.
- d) District Courts and Circuit Courts issue laws, while the Supreme Court enforces them.



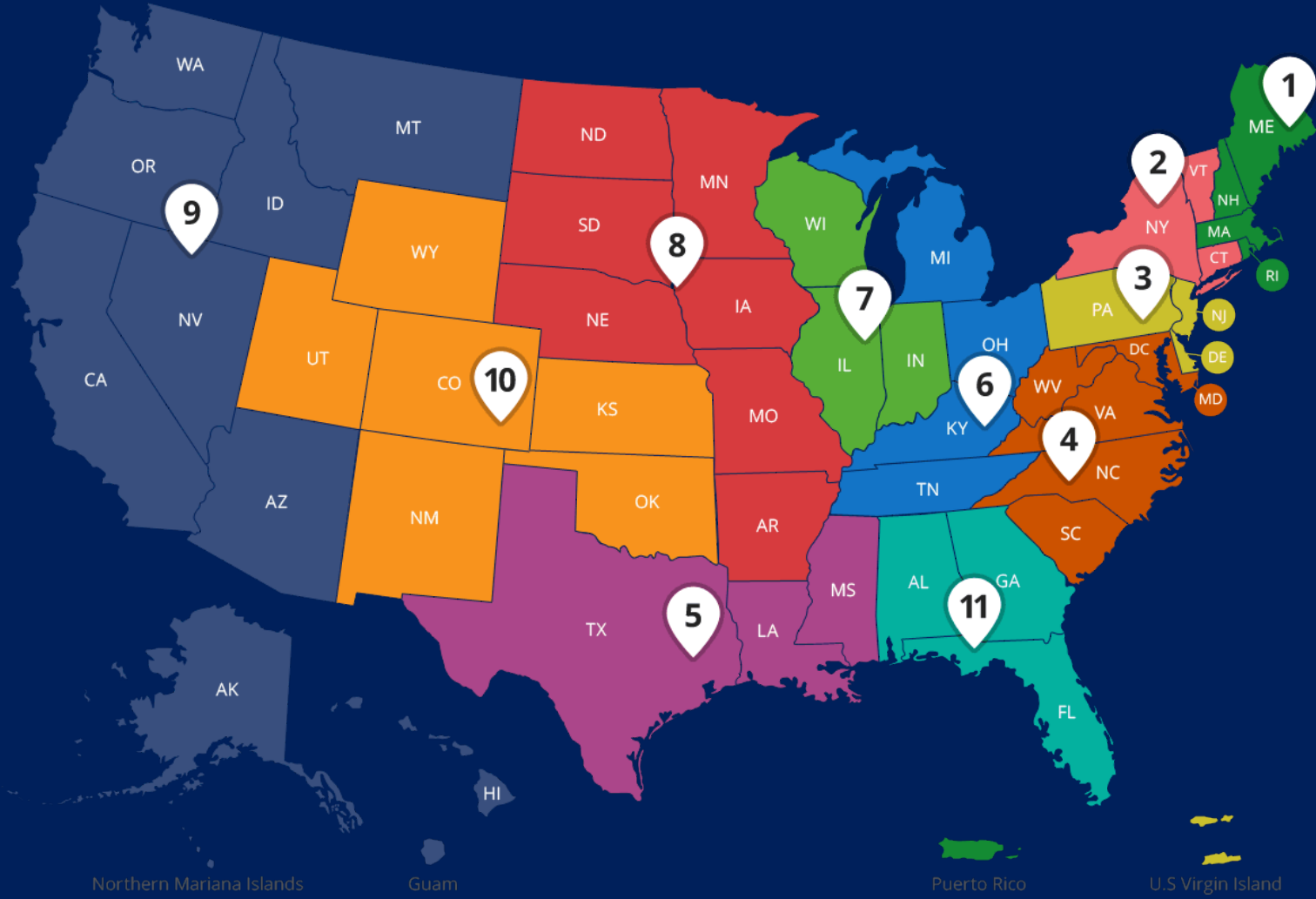
**Which of the following best delineates the roles of federal District Courts, Circuit Courts, and the Supreme Court?**

# Structure of the Federal Court System

- **District Courts (94):** Trial courts handling evidence, witnesses, and juries.
- **Circuit Courts (13):** Intermediate appellate courts resolving appeals from the district courts.
  - **Affirm:** Agree with the district court's decision, letting it stand.
  - **Reverse:** Overturn the district court's decision if legal errors are found.
  - **Vacate:** Nullify the lower court's judgment, effectively erasing it as if it never existed.
  - **Remand:** Send the case back to the district court for further proceedings, often with instructions on how to correct errors or reconsider specific issues.
    - Vacate and remand is a common outcome when the circuit court finds the lower court made a significant legal mistake or failed to follow proper procedures.
    - Sometimes, courts may remand without vacatur, meaning the agency's order or rule remains in effect while the agency addresses the court's concerns.
- **Supreme Court:** Final authority on federal law, hears ~1% of cases.



# Federal Circuits At A Glance



Source: <https://firstliberty.org/news/who-rules-america/>

# How the Supreme Court Selects Cases

- Supreme Court most commonly weighs in on:
  - Actual “circuit splits” or issues that the court anticipate will create circuit splits;
  - Key constitutional issues;
  - Rulings with nationwide implications (e.g., differing interpretations of Medicare reimbursement rules).
- *Certiorari* Process and the “Shadow Docket”
  - Requires 4 out of 9 justices vote to hear a case on the merits with full briefing and oral arguments.
  - The **shadow docket**, by contrast, often involves emergency requests like applications for stays or injunctions.
    - In *Roman Catholic Diocese of Brooklyn v. Cuomo*,<sup>1</sup> the Supreme Court struck down New York’s COVID-19 capacity limits on religious services.
    - The Court reversed lower court rulings that had upheld the restrictions.
    - The decision was unusual because the limits were no longer in effect and no ongoing harm could be shown.

<sup>1</sup> [Roman Cath. Diocese of Brooklyn v. Cuomo](#), 592 U.S. 14, 141 S. Ct. 63, 208 L. Ed. 2d 206 (2020)

# Summary

- **Federal courts have a three-level structure:** District Courts (trial), Circuit Courts (appeals), Supreme Court (final review).
- **Circuit Courts can affirm, reverse, vacate, or remand** lower court decisions, significantly impacting regulatory outcomes.
- **Circuit splits create legal uncertainty** and often prompt Supreme Court review.
- **Supreme Court takes cases with broad impact**, especially when circuits disagree or major legal principles are at stake.
- **Relevance:** Understanding this system is crucial for navigating regulatory developments in healthcare in an increasingly litigation-heavy environment

## Polling Question 2

### 2. What did the *Allina* decision hold with respect to the procedural requirements applicable to Medicare?

- a) CMS must provide notice-and-comment rulemaking whenever it issues any type of Medicare guidance, regardless of its effect.
- b) CMS must use notice-and-comment rulemaking when issuing Medicare policies that establish or change substantive legal standards, even if CMS characterizes them as interpretive rules.
- c) CMS can issue substantive Medicare policies without public notice-and-comment as long as they later seek public input informally.
- d) CMS is exempt from the Administrative Procedure Act when issuing Medicare payment rules, so long as the changes benefit providers.



**What did the Allina decision hold with respect to the procedural requirements applicable to Medicare?**



## Polling Question 3

### 3. What is the significance of the *Loper Bright* decision?

- a) It upheld Chevron deference for agency interpretations.
- b) It eliminated Chevron deference, limiting deference to the agency's "reasonable" interpretations of the statute.
- c) It required agencies to hold hearings before issuing rule.
- d) It expanded the ability of agencies to regulate healthcare independently.

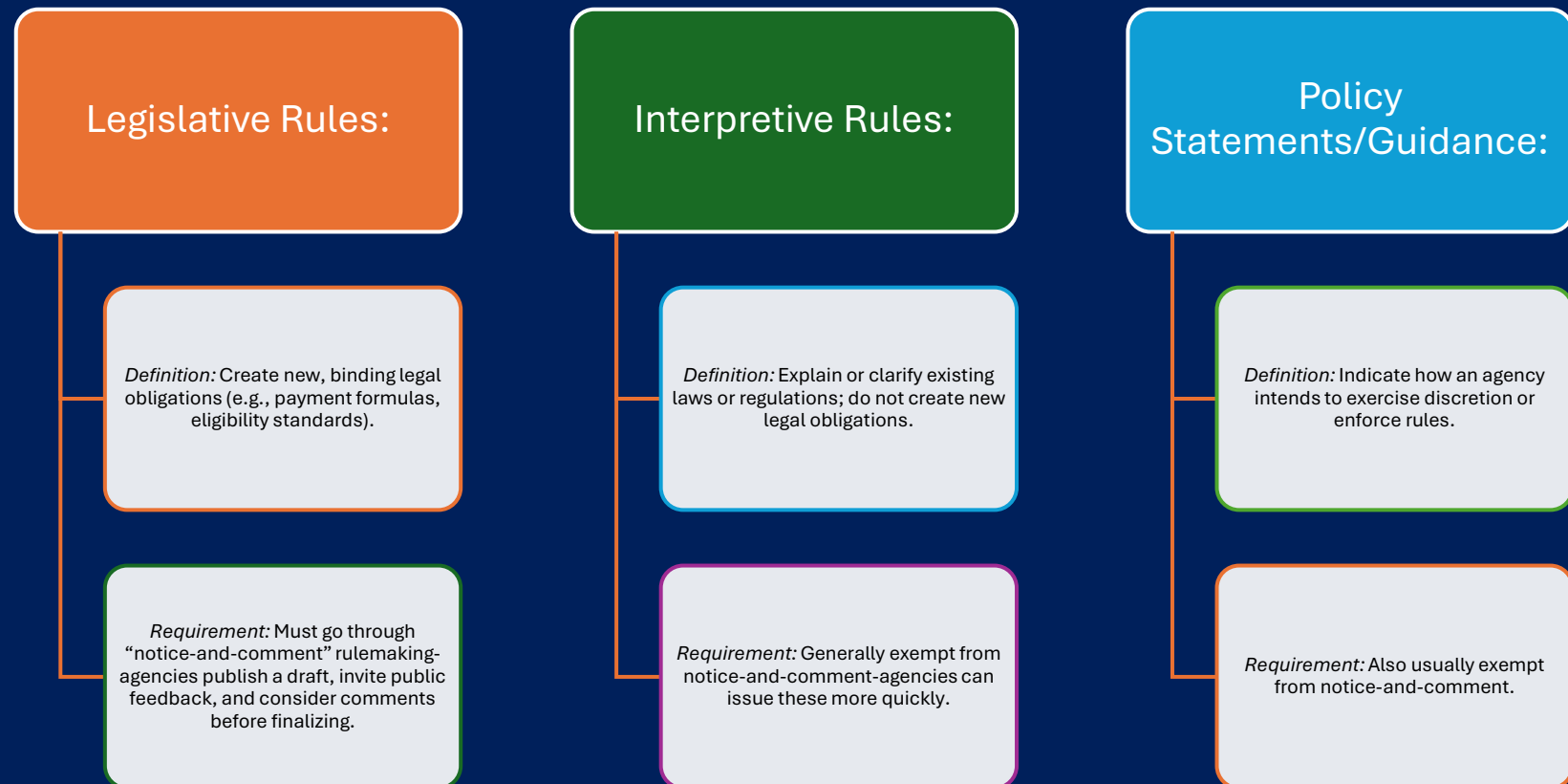


# What is the significance of the Loper Bright decision?

# The Administrative Procedure Act (APA) and Federal Agency Rulemaking - What You Need to Know

- The APA is the federal law that governs how agencies like CMS create regulations.
  - It's meant to ensure transparency, accountability, and public participation in the regulation-making process.

## Three Types Of Agency Actions



# Medicare's Extra Layer of Procedural Protections - Section 1871

- Section 1871 of the Social Security Act imposes a higher procedural standard for Medicare policies:
  - Requires notice-and-comment for any “substantive legal standard” affecting Medicare benefits or payments
  - This is broader than APA’s standard because it applies even to interpretive rules (which are not subject to notice-and-comment rulemaking under the APA) if they change a “substantive legal standard”
- *Azar v. Allina Health Services (2019)*<sup>1</sup>
  - CMS changed Medicare DSH payment formula without notice-and-comment, claiming it was an interpretive rule under the APA not subject to notice-and-comment.
  - Supreme Court held that CMS violated Section 1871 and that notice-and-comment was required because section 1871 does not expressly incorporate the “interpretive rule” exception of the APA.
  - CMS must use notice-and-comment rulemaking when issuing Medicare policies that establish or change substantive legal standards, even if CMS characterizes them as interpretive rules.

<sup>1</sup> [Azar v. Allina Health Servs.](#), 587 U.S. 566, 139 S. Ct. 1804, 204 L. Ed. 2d 139 (2019)

# Impact of *Allina* (2019) On Medicare

- **Notice-and-Comment Rulemaking Increase**
  - CMS must use notice-and-comment for more policies.
  - CMS has gone back and codified many of their policies in regulations rather than leaving them in Manual guidance.
  - Congress must now expressly waive notice-and-comment rulemaking for Medicare policies.
- **Operational and Strategic Effects**
  - CMS is less nimble in how quickly it can change its interpretation on issues since most policies now require formal rulemaking.
- **Opportunities for Stakeholders**
  - Greater transparency and input for stakeholders.
  - Increased ability to challenge abrupt Medicare policy changes.

# The Loper Bright Decision (2024) – End of Chevron Deference

- For 40 years, courts deferred to agency interpretations of ambiguous statutes under the *Chevron* doctrine.
- Loper Bright Enterprises v. Raimando (2024)<sup>1</sup>
  - Overturned *Chevron* in 6-3 decision authored by Chief Justice Roberts.
  - Ruled courts must exercise independent judgment in determining what statutes mean.
  - "Statutory ambiguity is not an implicit delegation to agencies."
  - Courts, not agencies, now have final say on legal interpretations.
- Significance for Healthcare
  - CMS can no longer rely on judicial deference for Medicare/Medicaid interpretations.
  - CMS must now defend the single "correct" reading of a statute, not just a "permissible" interpretation of it.
  - Policies lacking clear statutory foundation are vulnerable.

<sup>1</sup> Loper Bright Enters. v. Raimondo, 603 U.S. 369, 144 S. Ct. 2244, 219 L. Ed. 2d 832 (2024)

# Corner Post Decision – New Challenges to Old Regulations

- Corner Post v. Board of Governors of Federal Reserve System (July 2024)<sup>1</sup>:
  - Plaintiffs have six years from the date they are injured by a regulation to challenge it under the APA.
  - Clock starts when a party is affected, not when regulation is issued.
  - New market entrants can challenge longstanding regulations.
- Significance for Healthcare:
  - Well-established CMS regulations can face fresh legal challenges.
  - Regulations previously upheld under *Chevron* may be vulnerable to new challenges.
  - Creates regulatory uncertainty even for decades-old policies.

<sup>1</sup>Corner Post, Inc. v. Bd. of Governors of Fed. Rsrv. Sys., 603 U.S. 799, 144 S. Ct. 2440, 219 L. Ed. 2d 1139 (2024)

# Summary

- The APA establishes procedural requirements for how federal agencies create rules:
  - Legislative rules require notice-and-comment and create binding obligations.
  - Interpretive rules explain existing law and generally bypass notice-and-comment.
- Section 1871 of the Social Security Act, as interpreted in *Allina* imposes stricter requirements for Medicare policies, requiring notice-and-comment for any "substantive legal standard."
- *Loper Bright* eliminated Chevron deference, meaning courts will no longer defer to CMS interpretations of ambiguous statutes.
- *Corner Post* allows challenges to regulations up to six years after being affected by them, meaning even decades-old, established CMS regulations could face legal challenges
- **Relevance:** Understanding these rules clarifies whether and how CMS can act on its own and when Congressional action or advocacy is needed.



# Key Litigation in Healthcare

# *Dobbs v. Jackson Women's Health Organization (2022)*<sup>1</sup>

- **Summary.** The Supreme Court overturned *Roe v. Wade*, holding that the Constitution does not confer a right to abortion. This returned authority to regulate abortion to individual states.
- **Implications for Healthcare:**
  - **Access limitations:** Abortion is now unavailable or severely restricted in many states due to gestational limits or total bans.
  - **OB/GYN care disruption:** Providers in states like Texas face constraints in delivering reproductive and obstetric care (see Manatt study).
  - **Legal uncertainty for providers:** Fear of prosecution and unclear liability have led some to deviate from medical standards, particularly in emergencies.
  - **EMTALA conflicts:** Ongoing legal disputes over whether EMTALA preempts state abortion bans when emergency care requires abortion to stabilize a patient.

<sup>1</sup> Dobbs v. Jackson Women's Health Org., 597 U.S. 215, 142 S. Ct. 2228, 213 L. Ed. 2d 545 (2022)

# *Kennedy v. Braidwood Management*<sup>1</sup>



- **Summary.** This case challenges the ACA mandate requiring most private health plans to cover preventive services without cost-sharing. Plaintiffs argue that the U.S. Preventive Services Task Force (USPSTF), which recommends these services, was unconstitutionally appointed, violating the Appointments Clause.
- **Current Status:**
  - April 21, 2025: The Supreme Court heard oral arguments.
  - The Court is considering whether the USPSTF's structure violates the Appointments Clause.
- **Implications for Healthcare**
  - A ruling against the USPSTF could jeopardize no-cost coverage for a range of preventive services, including cancer screenings, immunizations, and PrEP.
  - Approximately 39 million Americans utilize at least one preventive service that could be affected.
  - The decision may prompt insurers to reintroduce cost-sharing for services previously covered without out-of-pocket expenses, potentially reducing access, especially among low-income populations.

<sup>1</sup> [Kennedy v. Braidwood Mgmt., Inc.](#), No. 24-316, 2025 WL 1200916 (U.S. Apr. 25, 2025)

# Sanofi, Novartis, and Eli Lilly v. HHS/HRSA



- **Summary.** Pharmaceutical manufacturers challenged HRSA’s authority to require 340B discounts for all contract pharmacies. They argued HRSA’s enforcement overstepped its statutory authority, as the 340B statute is silent on contract pharmacy use.
- **Current Status:**
  - 3rd Circuit (Sanofi): Ruled for the manufacturer — statute does not prohibit conditions on 340B distribution.<sup>1</sup>
  - D.C. Circuit (Novartis & United Therapeutics): Upheld limits on HRSA’s authority; manufacturers may impose reasonable conditions.<sup>2</sup>
  - 7th Circuit (Eli Lilly): Decision pending.<sup>3</sup>
- **Implications for Healthcare**
  - **For Manufacturers:** Affirmation of the ability to impose certain conditions on 340B drug distribution may lead to more controlled and potentially reduced use of contract pharmacies.
  - **For Covered Entities:** Potential limitations on access to discounted drugs through contract pharmacies could impact the financial viability of safety-net providers and their ability to serve underserved populations.
  - **For HRSA:** These rulings may necessitate a reevaluation of HRSA's enforcement strategies and guidance concerning the 340B program.

<sup>1</sup> *Sanofi Aventis U.S. LLC v. United States Dep't of Health & Hum. Servs.*, 58 F.4th 696 (3d Cir. 2023), judgment entered, No. 21-3167, 2023 WL 1325507 (3d Cir. Jan. 30, 2023)

<sup>2</sup> *Novartis Pharms. Corp. v. Johnson*, 102 F.4th 452 (D.C. Cir. 2024)

<sup>3</sup> *Eli Lilly & Co. v. United States Dep't of Health & Hum. Servs.*, No. 121CV00081SEBMJD, 2021 WL 5039566 (S.D. Ind. Oct. 29, 2021)

# *Novo Nordisk & AstraZeneca v. HHS*

- **Summary.** Pharmaceutical companies Novo Nordisk and AstraZeneca filed lawsuits challenging the Inflation Reduction Act’s Medicare Drug Price Negotiation Program. Among other claims, both companies argue that HHS and CMS violated the Administrative Procedure Act (APA) by implementing binding negotiation requirements without engaging in notice-and-comment rulemaking, and by exercising authority not clearly delegated by Congress.
- **Case Status**
  - Novo Nordisk<sup>1</sup>: A federal judge in New Jersey rejected the company's constitutional challenges, stating that participation in Medicare is voluntary and does not infringe upon the company's rights.
  - AstraZeneca<sup>2</sup>: A federal judge in Delaware dismissed the case, ruling that the company lacks a protected property interest in selling drugs to the government at prices it does not agree to pay.
  - Both companies have appealed their cases to the Third Circuit Court of Appeals, with decisions pending.
- **Implications for Healthcare**
  - **Deference to Statute vs. Process:** If courts uphold CMS’s approach, it may affirm that explicit statutory directives in the IRA can displace typical APA procedural requirements, such as notice-and-comment rulemaking — even for programs with significant economic impact.
  - **Bona Fide Marketing Standard:** AstraZeneca specifically cited CMS’s use of the “bona fide marketing” standard — which determines whether a drug qualifies for negotiation — as lacking formal rulemaking and sufficient statutory grounding. A favorable ruling for AstraZeneca could limit CMS’s use of interpretive criteria not directly traceable to the statute in future interpretations.

<sup>1</sup> Novo Nordisk Inc. v. Becerra, No. CV 23-20814 (ZNQ) (JBD), 2024 WL 3594413 (D.N.J. July 31, 2024)

<sup>2</sup> AstraZeneca Pharms. LP v. Becerra, 719 F. Supp. 3d 377 (D. Del. 2024), aff'd sub nom. AstraZeneca Pharms. LP v. Sec'y United States Dep't of Health & Hum. Servs., No. 24-1819, 2025 WL 1338088 (3d Cir. May 8, 2025)

# Advocacy

## Polling Question

### LQ4: What is an amicus curiae?

- a) A party directly involved in the case.
- b) A neutral expert who advises the judge.
- c) A "friend of the court" who submits arguments in favor of a specific position but is not a party to the case.
- d) A court-appointed lawyer for a defendant.



# What is an amicus curiae?



# Advocacy in the Shadow of Litigation



## Engage Through the Courts

File or support *amicus curiae* briefs (“friend of the court”) to provide clinical, economic, or access-related context to the court.

Coordinate with trade associations or coalitions to amplify impact.

Track lower court trends and circuit splits to anticipate national implications and prepare responses.



## Look Beyond the Judiciary

Engage Congress: Where courts highlight statutory ambiguity or overreach, request targeted legislative clarifications or fixes.

- Example: Congress could revise or define terms like “bona fide marketing” or 340B distribution rules post-litigation.

Work with state legislatures: In areas where federal statutory silence exists, or where federal authority is narrowed, states may step in (e.g., reproductive rights post-Dobbs).

# Turning Litigation into Policy Influence



## Monitor Legal Interpretations for Operational Exposure

Use litigation outcomes to reassess reliance on informal CMS guidance or gray areas of regulation.

Anticipate policy slowdowns where agencies face heightened APA scrutiny — identify where that creates risks or opportunities for your sector.



## Leverage Litigation Outcomes to Shape Future Rulemaking

Participate early in public comment processes, especially where litigation has forced an agency to codify previously informal policies.

Frame comments around judicial concerns (e.g., statutory limits, due process) to align with the evolving legal landscape.

# Post-Test



## Post-Test Question1

- 1. Which of the following best delineates the roles of federal District Courts, Circuit Courts, and the Supreme Court?**
- a) District Courts handle trials and legal disputes, Circuit Courts review appeals and may modify decisions, and the Supreme Court resolves select cases as the final authority.
  - b) Circuit Courts initiate trials, District Courts handle appeals, and the Supreme Court reviews all lower court decisions.
  - c) The Supreme Court conducts jury trials, Circuit Courts review constitutional issues, and District Courts focus solely on administrative cases.
  - d) District Courts and Circuit Courts issue laws, while the Supreme Court enforces them.



**Which of the following best delineates the roles of federal District Courts, Circuit Courts, and the Supreme Court?**

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### 2. What did the *Allina* decision hold with respect to the procedural requirements applicable to Medicare?

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**CMS must provide notice-and-comment rulemaking whenever it issues any type of Medicare guidance, regardless of its effect.**



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## Post-test Question 3

### 3: What is the significance of the *Loper Bright* decision?

- a) It upheld Chevron deference for agency interpretations.
- b) It eliminated Chevron deference, limiting deference to the agency's "reasonable" interpretations of the statute.
- c) It required agencies to hold hearings before issuing rule.
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# What is the significance of the Loper Bright decision?

## Post-test Question 3

**3: What is the significance of the *Loper Bright* decision?**

- a) It upheld Chevron deference for agency interpretations.
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## Post-test Question 4

### 4: What is an amicus curiae?

- a) A party directly involved in the case.
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# What is an amicus curiae?

## Post-test Question 4

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# Questions







# AMCP

Optimizing medicine.  
Improving lives.

## Lunch

Kingsman Park/Lincoln Park Room

**12:00pm – 1:00pm**



**AMCP**

Optimizing medicine.  
Improving lives.

# Legislative Asks Overview

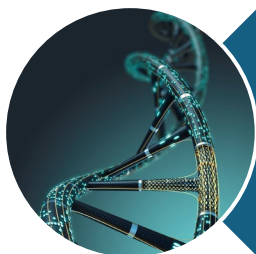
Tom Casey, AMCP

1:00pm – 2:00pm

# Our Legislative Priorities



Access to Prescription Digital Therapeutics (PDTs) Act (S. 1702/H.R. 3288)



Medicaid VBPs for Patients (MVP) Act (S. 1637)



Ensuring Community Access to Pharmacist Services (ECAPS) Act (H.R. 3164)

# Access to PDTs Act

## What the bill does:

1. Establishes a benefit category for PDTs under Medicare (Section 1861 of the Social Security Act) and Medicaid (Section 1905)
2. Directs CMS to establish appropriate payment methodologies for PDTs under Medicare Part B
3. Directs CMS to establish product-specific HCPCS codes for PDTs
4. Requires PDT manufacturers to report annually to HHS information on pricing, volume, and number of individual users
5. Establishes a definition for PDTs (see slide 5)

# Access to PDTs Act

## What the bill does NOT do:

- Mandate coverage of PDTs
  - CMS and state Medicaid plans would use existing authority to determine appropriate coverage of PDTs
  - CMS is not expected to consider PDTs a new therapeutic class for purposes of coverage determinations
- Establish a new Medicare “part”
  - The bill designates PDT coverage under Part B

# Access to PDTs Act

**Bill Status:** Introduced on May 8 in both chambers

- **S. 1702** led by Sens. Capito (R-WV) and Shaheen (D-NH)
  - Sens. Blackburn (R-TN), Booker (D-NJ), and Budd (R-NC) cosponsored last term
  - Referred to the Senate Finance Committee
- **H.R. 3288** led by Reps. Hern (R-OK-1) and Thompson (D-CA-4)
  - 25 additional cosponsors last term
  - Referred to the House Energy & Commerce and Ways & Means Committees

# Access to PDTs Act

## Background:


Prescription digital therapeutics (PDTs) are a type of digital health tool that meet the following conditions:

- Prescribed by a licensed health care provider,
- Indicated for the prevention, management, or treatment of a medical condition, disease, or disorder
- Primarily uses software to achieve its intended result, and
- Cleared or approved by the FDA

# Products Approved in the US since May 2021

DTx Target Many Disease States and are Very Quickly Expanding

Product Name	Indication	FDA Pathway
InTandemRx	Chronic Stroke	FDA 510(K) Exempt
ReadyAttention-Go	Attention	FDA 510(K) Exempt
Smileyscope	Acute Procedure Pain	FDA 510(K)
VRNT	Chronic Lower Back Pain	FDA 510(K)
MamaLift Plus	Postpartum Depression	FDA 510(K)
Rejoyn	Major Depressive Disorder	FDA 510(K)
CureSight	Amblyopia	FDA 510(K)
Endeavor OTC	Adult ADHD	FDA 510(K)
Regulora	IBS	FDA 510(K)
Leva Pevlic Health System	Incontinence	FDA 510(K)
Nerivio	Migraine	FDA De Novo
Luminopia One	Amblyopia	FDA De Novo
Stanza	Fibromyalgia	FDA De Novo
RelieVRx	Chronic Lower Back Pain	FDA De Novo
DaylightRx	Generalized Anxiety Disorder	FDA 510(K)
SleepioRx	Insomnia	FDA 510(K)

 Denotes Mental Health Products Covered by the DMHT Codes

 Denotes Mental Health Products NOT Covered by the DMHT Codes



# Access to PDTs Act

## PDT Examples:

- Luminopia – administers dichoptic therapy to children ages 4-7 with amblyopia (lazy eye) via VR headset
- ReSET/reSET-O – delivers cognitive behavioral therapy as an adjunctive therapy for substance use disorder treatment
- Rejoyn – six-week program of cognitive emotional training exercises to treat Major Depressive Disorder for adults who are on antidepressants

# Access to PDTs Act

- Commercial insurers and some government programs can already cover PDTs.
  - The Department of Veterans Affairs was an early adopter of PDTs, focused on products that treat mental health conditions
- AMCP has developed principles for PDT coverage and considerations for operational readiness. Barriers include:
  - Lack of standard coding and confusion over pharmacy vs. medical benefit
  - Evidentiary standards for device clearance vs. formulary coverage
  - Unique supply chain and reimbursement requirements

# Access to PDTs Act

- PDTs are eligible for Medicare reimbursement if they 1) are classified as durable medical equipment (DME); 2) qualify as a Digital Mental Health Treatment Device billed by an eligible practitioner; or 3) are labeled as a combination product by the FDA. **Many PDTs do not fit within these coverage pathways and need a benefit category to receive reimbursement under Part B.**
- State Medicaid programs have covered some PDTs under pilot programs. However, they must receive federal approval before they can offer access.

# Access to PDTs Act

## Impact on patients and providers:

- PDTs offer improved access to treatments for various conditions in communities that are underserved
  - [122 million](#) Americans live in Mental Health Care Health Professional Shortage Areas (HPSAs), concentrated in rural areas
  - Rural and low-income communities face geographic and socio-economic barriers to accessing treatment at a provider's office
- Providers get better monitoring of patient utilization and adherence to prescribed treatments, as well as more efficient use of office time

# MVP Act

## What the bill does:

- The MVP Act codifies the Multiple Best Price rule and clarifies how the “value-based price” is calculated. The bill defines the value-based price as the highest possible price, assuming all benchmarks are met.
- The bill exempts VBPs from the calculation of Medicare Average Sales Price and creates exclusions under the Anti-Kickback Statute and Average Manufacturer Price reporting.
- Finally, the bill directs HHS to issue guidance to states on options for entering into VBPs for inpatient drugs, including their ability to negotiate multi-state purchasing arrangements with manufacturers.

# MVP Act

## What the bill does NOT do:

- Require states to accept the terms of a VBP to cover an outpatient drug
- States can stick with the traditional best price. If a product is only offered under a VBP, HHS requires that states receive the minimum rebate amount, equal to 23.1 percent of the Average Manufacturer Price

# MVP Act

**Bill Status:** Introduced on May 7 in the Senate

- **S. 1637** led by Sens. Mullin (R-OK) and Hassan (D-NH); Sen. Scott (R-FL) also joined as an original cosponsor
  - Referred to the Senate Finance Committee
- House introduction is expected soon
  - Reps. Guthrie (R-KY-2) and Auchincloss (D-MA-4) expected to lead
  - Last term, the MVP Act had 42 House cosponsors
  - Rep. Guthrie is the Chair of the House Energy & Commerce Committee

# MVP Act

## Background:

- Specialty drugs are increasingly driving higher overall spending on prescription drugs
  - 80% of novel drug approvals in 2023 were specialty drugs
- Growing approvals of cell and gene therapies (CGTs) promise benefits and risks to all health plans, but particularly Medicaid programs that serve populations with complex conditions and must operate within state budgets
  - FDA has approved about 40 CGTs, and expects about 10 to 20 approvals per year going forward



# MVP Act

## Background:

- Medicaid programs cover patients who are the target populations of CGTs and other high-cost therapies
  - Medicaid covers 4 in 10 children in the country
  - In 2023, about 10% of adults with a history of cancer relied on Medicaid for health coverage
  - Medicaid programs cover an estimated 1.5 million people with rare diseases, though that number may be much higher when considering patients who are dually eligible for Medicare and Medicaid

# MVP Act

## Background:

- Under value- or outcomes-based purchasing arrangements (VBPs), manufacturers and payers align on pre-determined patient outcome benchmarks and tie payment amounts to those benchmarks
  - VBPs also require providers who administer treatment and other stakeholders necessary for successful execution
- VBPs can be structured in many ways, e.g. warranty models where part or all of a plan's payment is returned if the patient outcomes are not met vs. incremental payments as a patient reaches certain benchmarks

# MVP Act

## Why we need the bill:

- Increased use of VBPs may benefit states by
  - Improving coordination of care and patient access to novel therapies
  - Improving management of financial risk associated with covering novel therapies that have highly individualized outcomes
  - Replacing or bolstering existing supplemental rebate agreements with manufacturers
- States vary in their capacity to negotiate with manufacturers and other stakeholders

# MVP Act

## Multiple Best Price Reporting:

- In 2022, HHS finalized a rule that allowed manufacturers to report variable best prices under the best price provision of the Medicaid Drug Rebate Program.
- Under the rule, manufacturers may report the traditional fee-for-service best price and a “value-based” best price based on existing VBPs for any outpatient drug.
- The manufacturer must make the value-based price available to all states. However, states can choose to use the VBP or the fee-for-service best price.

# MVP Act

## Other payment models being tested:

- CMMI announced the Cell and Gene Therapy Access Model, which began on January 1, 2025; Sec. Kennedy announced that 35 states have opted into the model.
  - The pilot program is limited to 2 CGT products to treat sickle cell disease
  - CMS will negotiate multi-state purchasing arrangements with manufacturers on behalf of states that opt to participate in the model
  - Problems: 1) some states may be able to negotiate better deals with VBPs than CMS can secure, 2) states need more regulatory certainty than a pilot program can afford when entering into arrangements for products that cost \$2 million+ for one course of treatment

# MVP Act

## Alignment with Drug Pricing EO:

- For Republican offices, you may highlight that the MVP Act aligns with President Trump's priority to promote innovation and value in Medicaid
- On April 15, Trump issued an Executive Order (EO) titled, "Lowering Drug Prices by Once Again Putting Americans First"
- Section 6 directs OMB, the Domestic Policy Council, and HHS to provide recommendations on how to promote innovation in Medicaid drug payment methodologies, link payments for drugs to the value obtained, and support States in managing drug spending within 180 days
- *"Congress can provide President Trump a win by passing the MVP Act"*

# ECAPS Act

**Bill Status:** Introduced on May 1 in the House

- H.R. 3164 led by Reps. Smith (R-NE-3), Schneider (D-IL-10), Harshbarger (R-TN-1) and Matsui (D-CA-7)
  - Bill has 12 cosponsors currently, but there were 148 cosponsors in the last term
  - Referred to the House Ways & Means and Energy & Commerce Committees
- Senate introduction is expected soon
  - Leads last term were Sens. Thune (R-SD) and Warner (D-VA); 29 cosponsors

# ECAPS Act

## Background:

- Pharmacists play a key public health role as the most accessible health care professionals
  - About 90% of Americans live within 5 miles of a pharmacy
  - Patients visit their community pharmacy twice as often as their primary care provider
  - Pharmacy teams administered 74% of influenza, COVID-19, and RSV vaccines during the 2023-2024 respiratory season
  - Over three-quarters of community pharmacies serve populations of 50,000 or fewer



# ECAPS Act

## The Problem:

- Pharmacists can't bill Medicare Part B for pharmacy care services that are authorized under state scope-of-practice laws, which limits patient access to tests and treatments for respiratory illnesses.
- HHS granted pharmacists the authority to provide essential pharmacy services during the public health emergency and bill Medicare Part B, but many of those authorities have expired.

# ECAPS Act

## What the bill does:

- The ECAPS Act amends the Social Security Act to permanently authorize Medicare Part B coverage of pharmacist services related to testing or treatment for RSV, strep throat, the flu, and COVID-19, consistent with state laws.
- The bill authorizes payment equal to 80% of the lesser of the actual charge for the services or the Part B rate for physicians.
- The bill also expands the federal government's ability to authorize essential pharmacy services in response to future public health emergencies.

# ECAPS Act

## What the bill does NOT do:

- The bill does not supersede state scope-of-practice laws. The bill text stipulates that Part B coverage only extends to essential pharmacy services that are consistent with the pharmacists' licenses or are pursuant to a federal emergency authority.
- Previous versions included coverage and payment for pharmacist administration of the COVID-19 vaccine. That's been removed since CMS decided to align coverage and payment with other Part B preventive vaccines starting this year.



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Improving lives.

**Break**  
**2:00pm-2:30pm**





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## Hill Meeting How-To:

Andrew McKechnie

Tiber Creek Group

**2:30pm – 3:00pm**



# Lobbying 101

**TIBER CREEK GROUP**





# The “Dos” of Lobbying

- **Introduce yourself/your company briefly. Practice your “elevator speech.”**
- **Be patient and flexible. Members and staff are busy and their schedules can be unpredictable. Don’t be offended if your meeting is in the hall or on the go.**
- **Be confident and concise.**
- **Go local. If you have a connection to the state or district, mention it. Don’t promise your company is going to operate in their state or district in the future unless you’re sure it will happen.**
- **Be prepared for questions. If you don’t know the answer, no worries. Just let staff know you’ll follow up.**
- **Be aware of the office you’re in. Your pitch may be a bit different depending on who you’re meeting with.**



## The “Don’ts” of Lobbying

- **Be late or skip a meeting.** Make sure you get to your meetings and alert the office if you’re running late.
- **Be overly partisan or negative.** We want to leave a positive impression.
- **Be offended if the meeting is quick.** Members and staffers are pulled in a million directions and meetings are sometimes pretty quick.
- **Worry if you can’t answer a question or are unsure of the answer.** Admit it and say, “I’ll look into that and get back to you.”
- **Tell the office that you supported the Member’s campaign.** Avoid talking about campaigns entirely during official meetings.



## Meeting flow

The meeting lead should introduce themselves and their then company members introduce themselves/their companies.

Ask if there are any questions.

Before the meeting, decide within your group who is going to kick off the discussion and who will make “the ask.”

Make the ask.

And finally, thank the Member or staffer for their time.



## When making your pitch:

- **Use examples or stories to emphasize why [your issue] matters.**
- **Too many numbers can get in the way. Make sure they're compelling and comprehensible.**
- **Don't use jargon.**
- **Be clear about the “ask.”**
- **Be open to questions.**



## The follow-up:

- **Email a thank-you after the meeting.**
- **In addition to expressing your thanks, repeat the “ask.”**
- **Answer any questions raised during the meeting you were unable to address at the time.**
- **Be sure to provide any materials you promised to provide.**



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## State of Play

Andrew McKechnie

Tiber Creek Group

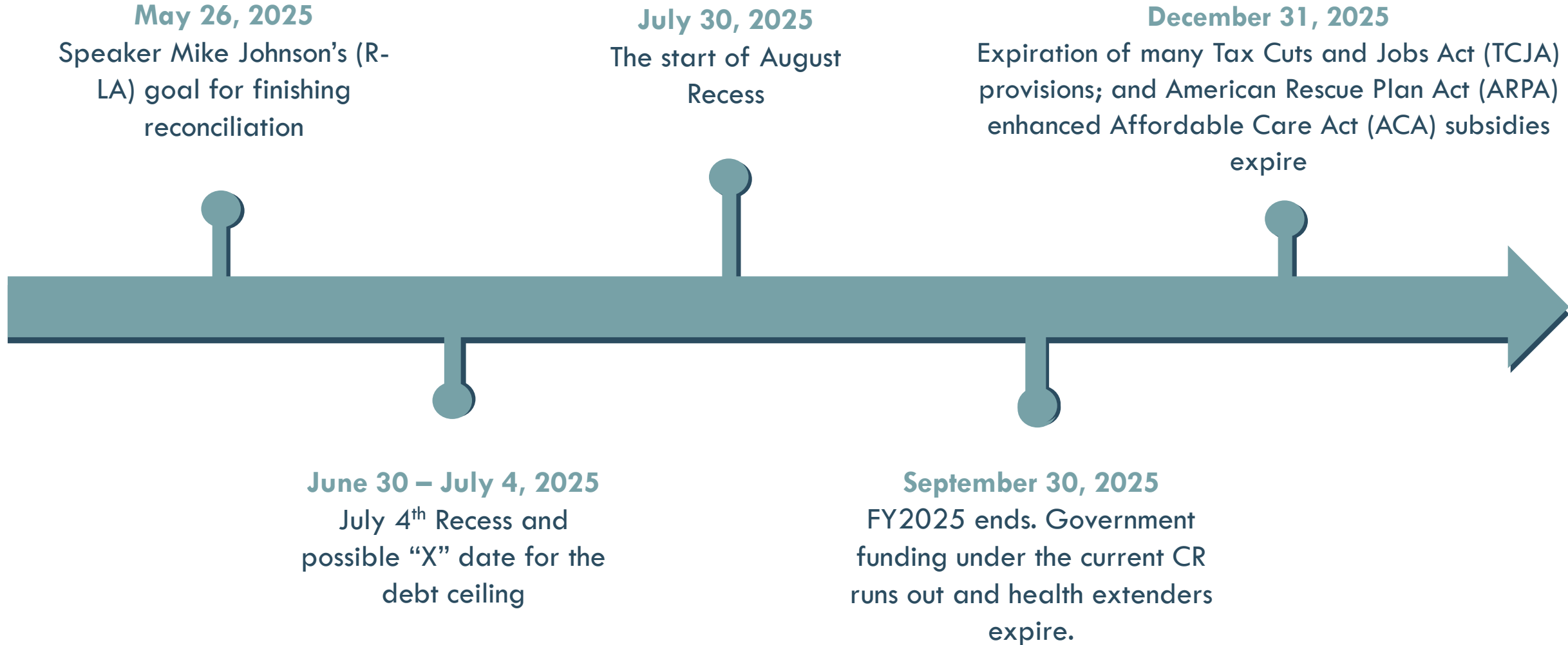
3:00pm – 3:30pm

# Tiber Creek Group

2025 POLICY OUTLOOK



# KEY DATES



# THE TRUMP ADMINISTRATION



5 Bills Signed  
Into Law

56 Nominees  
Confirmed

The First  
100



143 Executive  
Orders  
Signed

Days



8 National  
Emergencies  
Declared

See TCG's EO  
Tracker, [here](#)



6

Section 232  
Investigations  
Opened

See TCG's First 100 Days  
in Trade, [here](#)

200+

and counting

Lawsuits against the  
Trump Administration



\$160  
billion

in DOGE Savings\*

According to the DOGE Website, [here](#)

107

Biden-era  
Executive  
Orders  
Revoked



# MAJOR HEALTHCARE EOs



## EXECUTIVE ORDER

*13 February 2025*

### Establishing the President's Make America Healthy Again Commission

- Establishes the Make America Healthy Again Commission, focusing on chronic disease research, nutrition, and increased treatment and coverage options.
- The Commission shall develop an assessment to "Make Our Children Healthy Again" by **May 24** and a related strategy by **Aug. 12**



## EXECUTIVE ORDER

*25 February 2025*

### Making America Healthy Again by Empowering Patients with Clear, Accurate, and Actionable Healthcare Pricing Information

- Requires, within 90 days (**May 26**) HHS, DOL, and Treasury to take steps to:
  - require disclosure of actual prices for items and services
  - issue guidance/regulations on
    - information standardization
    - transparency rule enforcement policies

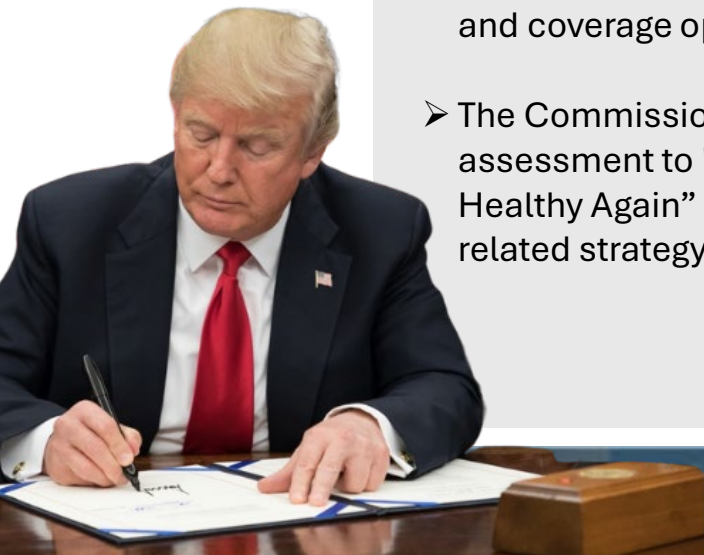


## EXECUTIVE ORDER

*15 April 2025*

### Lowering Drug Prices by Once Again Putting Americans First

- Among other policies, aims to lower drug prices by:
  - Reforming the Medicare Drug Price Negotiation Program (**June 14**)
  - Addressing PBM transparency (**July 14 & Oct. 12**)
  - Testing value-based payment for drugs in Medicare (**Apr. 2026**)
  - Reforming Medicare payment (**Oct. 12**)
  - Promoting innovation in Medicaid drug payment (**Oct. 12**)



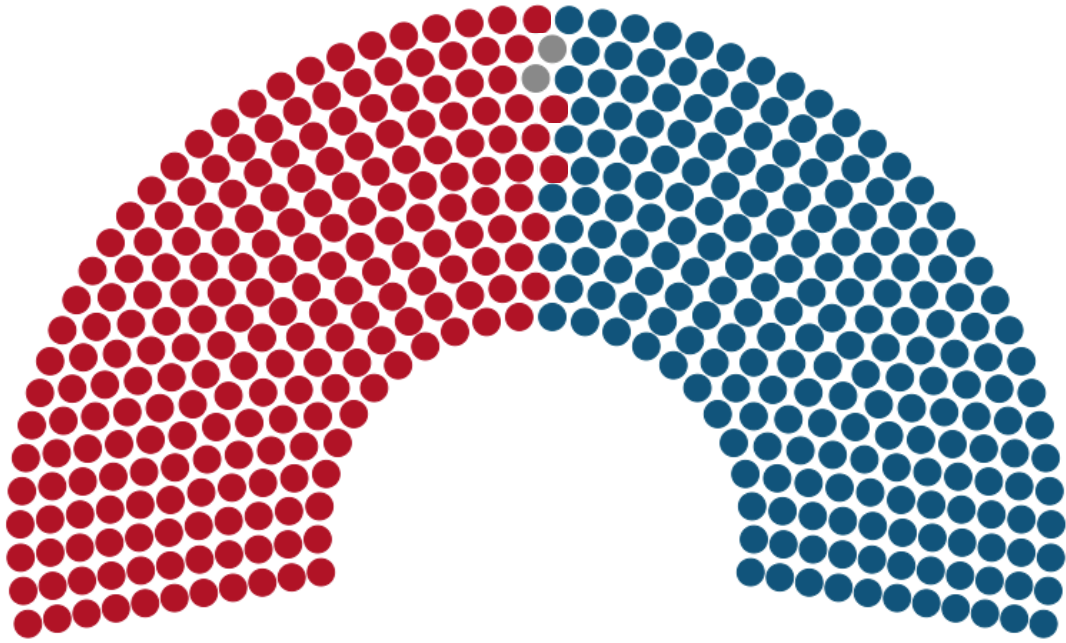
# TRUMP ADMINISTRATION FOCUS AREAS

REGULATORY RELIEF	GOVERNMENT REFORM	REDUCING COSTS/SPENDING	MAHA
<ul style="list-style-type: none"> <li>• <b>Regulatory “Red Tape Relief”</b></li> <li>• <b>Rescinding Biden AI Executive Order</b></li> <li>• <b>Reducing Provider Reporting Requirements</b></li> <li>• <b>Promoting Domestic Manufacturing</b></li> </ul>	<ul style="list-style-type: none"> <li>• <b>Establishing Department of Government Efficiency (DOGE)</b></li> <li>• <b>Reforming Public Health Agencies</b></li> <li>• <b>“Radical Transparency” at HHS</b></li> <li>• <b>Reducing the Federal Workforce</b></li> <li>• <b>Updating IT systems</b></li> <li>• <b>More political appointees instead of career staff</b></li> </ul>	<ul style="list-style-type: none"> <li>• <b>Medicaid Reforms</b></li> <li>• <b>Medicare Advantage Reforms</b></li> <li>• <b>Drug Pricing and PBM Reforms</b></li> <li>• <b>Site Neutral Payment Changes</b></li> <li>• <b>Lower Cost Insurance Options</b></li> <li>• <b>Streamlining CMMI Demos</b></li> </ul>	<ul style="list-style-type: none"> <li>• <b>Refocus NIH and FDA to research the relationship between food additives and chronic disease</b></li> <li>• <b>Make nutrition a bigger part of Medicare and Medicaid</b></li> <li>• <b>Greater focus on prevention and promoting healthy behaviors</b></li> <li>• <b>Address over medication</b></li> </ul>

# 119<sup>TH</sup> CONGRESS



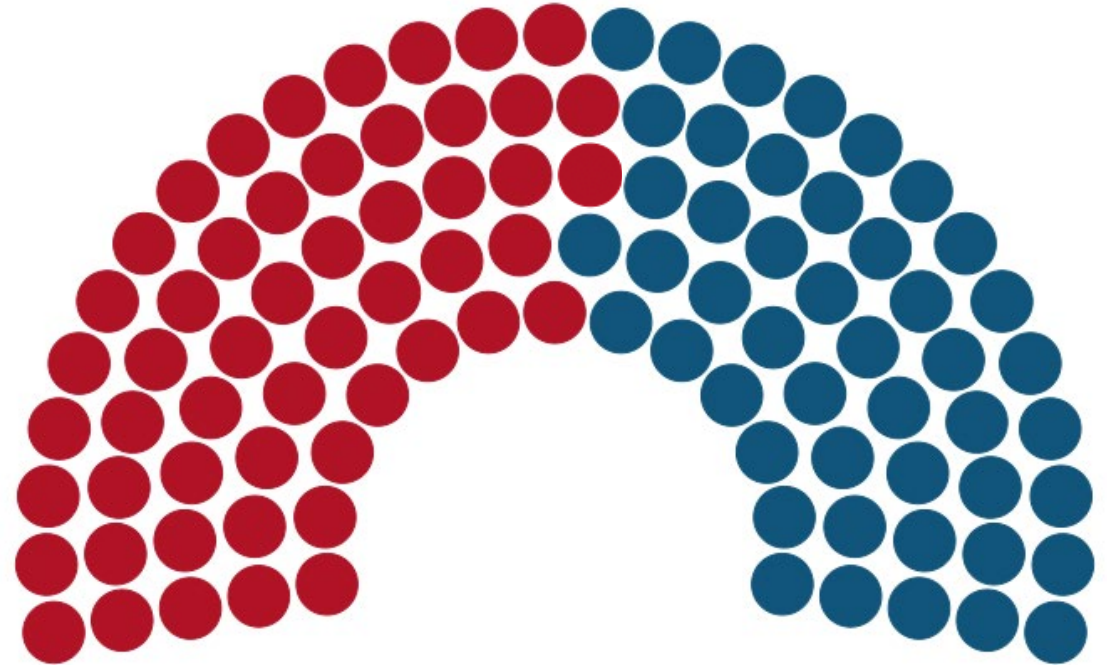
# 119<sup>th</sup> CONGRESS: Current Balance of Power



## House of Representatives

Current Control: **220** | **213**

*2 Vacancies*



## U.S. Senate

Current Control: **53** | **47**

# CONGRESSIONAL OUTLOOK

## Reconciliation Bill

- Extremely challenging given tight margins and different factions
- Medicaid is key focus area

## Government Funding

- Deadline is Sept 30<sup>th</sup>
- Several health extenders also expire Sept 30<sup>th</sup>
- Going to be very difficult to reach a bipartisan agreement

## Everything Else

- Physician payment reform
- Medicare Advantage reform
- Drug Pricing and PBM reform
- Dual eligible reform

# QUESTIONS & DISCUSSION

# APPENDIX



# FY26 SKINNY BUDGET

The President's "skinny budget" request proposes to reduce base discretionary funding to HHS by \$33B, or 26.2%.



**+\$500M**

For the MAHA initiative, to tackle a wide range of priorities, including nutrition, healthy lifestyles, overreliance on medication, and food and drug quality and safety.



**- ~\$3.6B**

From CDC, to refocus the agency on its "core activities:" emerging and infectious disease surveillance, outbreak investigations, and maintaining public health infrastructure.



**- ~\$18B**

From NIH, to reform and align NIH research activities with MAHA, including by consolidating programs into five focus areas: body systems, neuroscience and the brain, general medical sciences, disabilities, and behavioral health.



**-\$674M**

From CMS, to eliminate spending on "non-statutory, wasteful, and woke activities," with "no impact on providing benefits to Medicare and Medicaid beneficiaries."

# CONGRESSIONAL MEMBERS TO WATCH

## *Senate HELP Committee*



*Bill Cassidy (R-LA)*



*Bernie Sanders (I-VT)*

## *Senate Finance Committee*



*Mike Crapo (R-ID)*



*Ron Wyden (D-OR)*

## *Leadership*



*John Thune (R-SD)*



*Charles Schumer (D-NY)*

# CONGRESSIONAL MEMBERS TO WATCH

## *House Energy and Commerce Committee*



*Brett Guthrie (R-KY)*



*Frank Pallone (D-NJ)*

## *House Ways and Means Committee*



*Jason Smith (R-MO)*



*Richard Neal (D-MA)*

## *Leadership*



*Mike Johnson (R-LA)*



*Steve Scalise (R-LA)*



*Hakeem Jeffries (D-NY)*

# TRUMP HEALTH TEAM



**Robert F. Kennedy, Jr.,**  
*HHS Secretary*



**Dr. Mehmet Oz,**  
*CMS Administrator*



**Dr. Marty Makary,**  
*FDA Commissioner*



**Dr. Jay Bhattacharya,**  
*NIH Director*



**Jim O'Neill,**  
*HHS Deputy Secretary*



**Abe Sutton,**  
*CMMI Director*



**Chris Klomp,**  
*Center for Medicare  
Director*



**Drew Snyder,**  
*Center for Medicaid  
& CHIP Director*



**Theo Merkel,**  
*Special Assistant,  
Domestic Health*



**Joel Zinberg,**  
*Special Assistant,  
Economic Policy*



**Don Dempsey,**  
*OMB Associate  
Director, Health Care*



**AMCP**

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# Leave-behind Distribution & Meeting Practice

3:30pm – 4:30pm

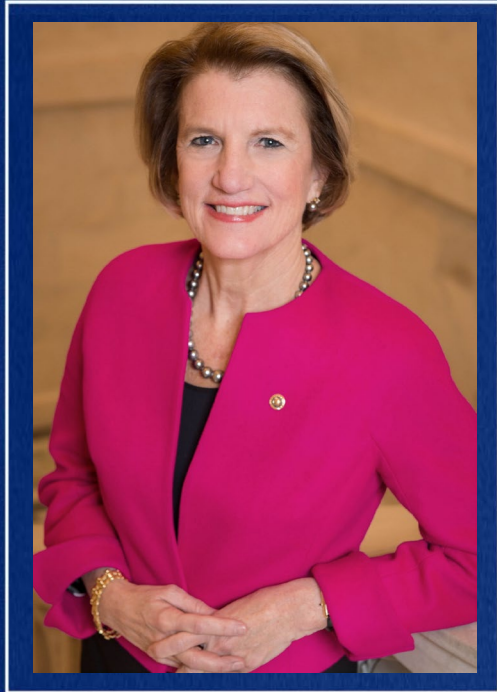
WELCOME TO THE



AMCP

CAPITOL DINNER

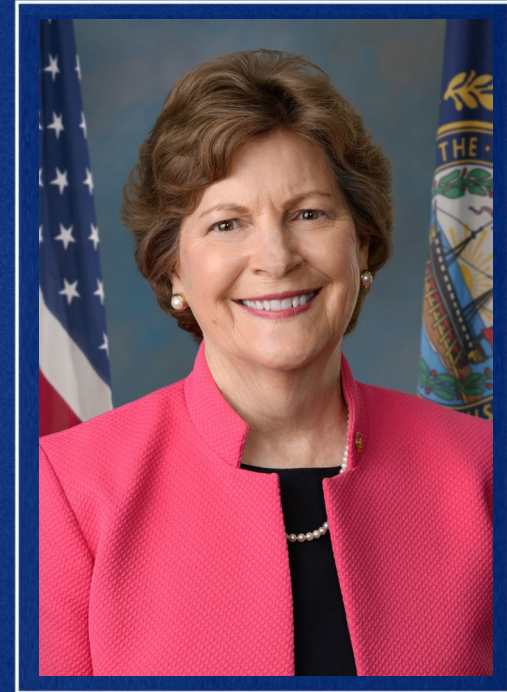




**SENATOR SHELLEY  
MOORE CAPITO**

**&**

**SENATOR JEANNE  
SHAHEEN**



**2025 AMCP ACHIEVEMENT IN PHARMACY  
POLICY AWARD HONOREES**